TAILOR MADE
COMPOUNDING

PEPTIDE GUIDE
Tailor Made Compounding, launched in the US in January of 2016 and have since made it a priority to expose our prescribers to the opportunities and application of peptide medicine in the integrative space.

Since our inception, we have quickly established ourselves as one of the top compounding pharmacies in the nation. Achieved through our compounding expertise, knowledge, and experience. Together, with our sister pharmacies around the world, we enjoy a well-known reputation for working closely with our physicians and being not only subject matter experts but problem solvers for hard to source and hard to compound pharmaceuticals. Our sister facility, Como Compounding in Melbourne, has been working with peptide therapies for over a decade. After seeing the success these products were having for doctors and patients, we saw the intense need for a reputable source of peptides in the United States.
At Tailor Made we pride ourselves in being a key resource to practitioners and their staff, always keeping up with the literature and the cutting edge, ever changing peptide therapy market. We have built on that foundation, by being the first in the United States to offer compounds like the CJC 1295, Bremelanotide PT 141, BPC-157, and Epitalon. Since then, we have pioneered the sourcing and compounding of over 40 unique prescription peptides and are constantly adding to our formulary. As we help make new products available in the United States we also help teach doctors on their clinical indications and their dosing. We highly value our relationships with prescribers to provide peptide education and expertise to physicians, Nurses, PAs, and patients looking to add new and exciting tools to their repertoire.

Through our great relationships and outstanding products we have also began to expand our reach further. Our promise to you, our customer, is to continue to be on the forefront and be the “first movers” with knowledge, support and new products. Together, all of our locations aim to positively disrupt medicine, using innovative technologies through education, partnership and continuing investment in research and development.
DESCRIPTION

3-Desoxy DHEA is a competitive aromatase inhibitor for use in controlling estrogen and increasing endogenous testosterone production. This compound is shown to potently reduce aromatase activity through binding to the enzyme and blocking access to endogenous estrogen precursors (androstenedione, testosterone). The competitive aromatase inhibition works differently than suicide substrate inhibition. The competitive inhibition offers a more short term solution to estrogen control, as aromatase inhibition only occurs while 3-Desoxy DHEA is present in the body. 3-Desoxy DHEA is a relatively quickly metabolized compound and has an excellent potency with IC50 and Ki values. 3-Desoxy DHEA offers you a new option for estrogen control and natural testosterone elevation along with a high potency coupled with better dose control.

PROTOCOL

Content & Potency: 100mg capsules provided in quantity of 30.
Suggested dosage: Take 1 capsule by mouth once daily.

CLINICAL RESEARCH

What is desoxy-DHEA and How Does it Work?
Ben Esgro, BS, CSCS, CISS

Although Desoxy DHEA is an effective competitive inhibitor of aromatase it is not nearly as potent as SERMs or other steroidal and non-steroidal suicide inhibitors. The structure-activity relationships mentioned are not comprehensive as there undoubtedly exists additional structural manipulations that occur to further enhance aromatase affinity. Therefore, it is NOT an appropriate replacement to prescription compounds when heavy aromatase inhibition is required. It does however, offer a cost-effective, safe, and legal method of estrogen management as validated by independent lab tests and selected in vitro data. Competitive aromatase inhibition works differently than suicide substrate inhibition, which is the mode of action through which other over the counter aromatase inhibitors such as 6-OXO and ATD work. Competitive inhibition offers a more short term solution to estrogen control, as aromatase inhibition only occurs while Desoxy DHEA is present in the body. Desoxy DHEA is a relatively quickly metabolized compound. So with Desoxy DHEA Tailor Made offers you a new option for estrogen control.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Amlexanox is an anti-inflammatory and anti-allergic compound which has traditionally been used to treat ulcers by reducing healing time and pain. It has multiple mechanisms of action such as inhibit inflammation by inhibiting the release of histamine and leukotrienes. It has been shown to selectively inhibit TBK1 and IKK-ε, producing reversible weight loss and improved insulin sensitivity. It is through this mechanism that it has produced substantial results in terms of reducing HbA1C levels and increase insulin sensitivity.

PROTOCOL

Content & Potency: 40mg capsules provided in a quantity of 90.
Suggested dosage: Take one capsule by mouth once daily.

CLINICAL RESEARCH

Inhibition of IKK 3and TBK1 Improves Glucose Control in a Subset of Patients with Type 2 Diabetes

Numerous studies indicate an inflammatory link between obesity and type 2 diabetes. The inflammatory kinases IKK 3and TBK1 are elevated in obesity; their inhibition in obese mice reduces weight, insulin resistance, fatty liver and inflammation. Here we studied amlexanox, an inhibitor of IKK 3and TBK1, in a proof-of-concept randomized, double-blind, placebo-controlled study of 42 obese patients with type 2 diabetes and nonalcoholic fatty liver disease.

Treatment of patients with amlexanox produced a statistically significant reduction in Hemoglobin A1c and fructosamine. Interestingly, a subset of drug responders also exhibited improvements in insulin sensitivity and hepatic steatosis. This subgroup was characterized by a distinct inflammatory gene expression signature from biopsied subcutaneous fat at baseline. They also exhibited a unique pattern of gene expression changes in response to amlexanox, consistent with increased energy expenditure.

Together, these data suggest that dual-specificity inhibitors of IKK 3and TBK1 may be effective therapies for metabolic disease in an identifiable subset of patients.
DESCRIPTION

Ammonium tetrathiomolybdate (TM) was developed as a non-toxic treatment for Wilson’s disease, which is a condition that results in copper buildup in the body. Tetrathiomolybdate binds both food copper and endogenously produced copper and prevents their absorption when taken with food. When taken without food it enters the blood and binds with available copper to prevent it being used by cells. Tetrathiomolybdate has also shown to be a promising treatment for cancer. Copper is involved in turning on the growth of new blood vessels that tumors depend on for growth. By depriving the tumors of the copper supply that is needed for new blood vessels, the growth may be slowed or stabilized. It has also been shown to target the copper transporter ATP7A and enhance the sensitivity of breast cancer to Cisplatin treatment, as well as, decreasing the development of resistance to cisplatin.

PROTOCOL

Content & Potency: 40mg capsules provided in a quantity of 90.
Suggested dosage: Take one capsule by mouth three times daily between meals.

CLINICAL RESEARCH

Ammonium tetrathiomolybdate treatment targets the copper transporter ATP7A and enhances sensitivity of breast cancer to cisplatin

Cristine L. Chisholm, #2 Haitao Wang, #1 Ada Hang-Heng Wong, 1 Guelaguetza Vazquez-Ortiz, 2 Weiping Chen, 3 Xiaoling Xu, 1 and Chu-Xia Deng 1,2

Abstract

Cisplatin is an effective breast cancer drug but resistance often develops over prolonged chemotherapy. Therefore, we performed a candidate approach RNAi screen in combination with cisplatin treatment to identify molecular pathways conferring survival advantages. The screen identified ATP7A as a therapeutic target. ATP7A is a copper ATPase transporter responsible for intercellular movement and sequestering of cisplatin. Pharmaceutical replacement for ATP7A by ammonium tetrathiomolybdate (TM) enhanced cisplatin treatment in breast cancer cells. Allograft and xenograft models in athymic nude mice treated with cisplatin/TM exhibited retarded tumor growth, reduced accumulation of cancer stem cells and decreased cell proliferation as compared to mono-treatment with cisplatin or TM. Cisplatin/TM treatment of cisplatin-resistant tumors reduced ATP7A protein levels, attenuated cisplatin sequestering by ATP7A, increased nuclear availability of cisplatin, and subsequently enhanced DNA damage and apoptosis. Microarray analysis of gene ontology pathways that responded uniquely to cisplatin/TM double treatment depicted changes in cell cycle regulation, specifically in the G1/S transition. These findings offer the potential to combat platinum-resistant tumors and sensitize patients to conventional breast cancer treatment by identifying and targeting the resistant tumors’ unique molecular adaptations.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Aniracetam employs a similar method of action to other racetams. It has been shown to specifically stimulate the AMPA receptor site. The AMPA receptor is the most common glutamate activated receptor associated with the Central Nervous System and its functions. AMPA receptors play a role in learning and memory formation. Aniracetam seems to have a higher affinity with the AMPA receptors than other racemic compounds.

Another interesting action of Aniracetam is the observed anxiety reducing effects. It completes this action without causing sedation and the anxiolytic benefit of the substance has been extensively studied in animal models. This anxiolytic response is believed to be caused in part, by activation of the D2 and D3 dopamine receptors. Nicotinic Ach receptor activation is also believed to contribute to anxiolytic effects and nootropic effects. Additionally, Aniracetam seems to enact on the 5-HTP(2a) receptor which helps to process Serotonin and may further advance anxiolytic/antidepressant functions.

PROTOCOL

Content & Potency: 375mg capsules provided in a quantity of 60.
Suggested dosage: Take two capsules by mouth every morning with food for 30 days.

CLINICAL RESEARCH

Clinical Efficacy of Aniracetam, Either as Monotherapy or Combined with Cholinesterase Inhibitors, in Patients with Cognitive Impairment: A Comparative Open Study*

Chrysi C. Koliaki, Chaido Messini & Magda Tsolaki

Introduction: Dementia constitutes an increasingly prevalent cognitive disorder with serious socioeconomic implications. Aims: In the present study, we aimed to evaluate the efficacy of aniracetam, either as monotherapy or combined with cholinesterase inhibitors (ChEIs), in terms of several neuropsychological parameters, in a considerable number of patients with dementia. Results: In our prospective, open-label study, we enrolled a total of 276 patients (mean age 71 ± 8 years, 95 males) with cognitive disorders. Our study population comprised four groups: no treatment group (n = 75), aniracetam monotherapy group (n = 58), ChEIs monotherapy group (n = 68), and group of combined treatment (n = 68). Patients were examined with validated neuropsychological tests at baseline, 3, 6, and 12 months of treatment. In patients treated with aniracetam, all studied parameters were adequately maintained at 6 and 12 months, while emotional state was significantly improved at 3 months. In patients treated with ChEIs, we observed a significant cognitive deterioration at 12 months. The comparison between aniracetam and ChEIs in patients with relatively mild dementia (15 ≤ MMSE ≤ 25) revealed a significantly better cognitive performance with aniracetam at 6 months and improved functionality at 3 months. Comparing aniracetam monotherapy with combined treatment in the same population, aniracetam performed better in the cognitive scale at 6 months, and displayed a notable tendency for enhanced mood at 12 months and improved functionality at 6 months. Conclusions: Our findings indicate that aniracetam (a nootropic compound with glutamatergic activity and neuroprotective potential) is a promising option for patients with cognitive deficit of mild severity. It preserved all neuropsychological parameters for at least 12 months, and seemed to exert a favorable effect on emotional stability of demented patients.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.

Tailor Made Compounding | Ph: 1 859 887 0013 | admin@tailormadecompounding.com
AOD9604 is the a GH fragment which comprised the last 16 amino acids of the larger growth hormone molecule. Although originally studies for fat loss, further studies have transitioned it for regenerative medicine. In combination with hyaluronic acid (HA), it is now being used to help regenerate hyaline cartilage and is showing strong efficacy in the treatment of osteoarthritis. The combination acts to enhance the differentiation of adipose mesenchymal stem cells into bone, promote proteoglycan and collagen production in chondrocytes, and promote differentiation of myoblasts into C2C12 cells; all of which are essential for bone, cartilage, and muscle repair. These studies indicate that it has stronger therapeutic benefits compared to Bone Marrow Aspirate Concentrate (BMAC) and Platelet Rich Plasma (PRP) therapy, which have also been emerging as candidates for osteoarthritis medications.

AOD9604 + HA has proceeded to human WOMAC trials which allow the combination to be investigated for on an osteoarthritis index which considers pain, stiffness, and functionality on a variety of scores.

**PROTOCOL**

**Content & Potency:** AOD 1000mcg/ml + HA 10mg/ml intra-articular injectable provided in a 5ml vial.

**Suggested dosage:** 0.5-0.75m injected intra-articularly by a medical professional once a week for 4 weeks, then once a month for 5 months.

**CLINICAL RESEARCH**


**Effect of Intra-articular Injection of AOD9604 with or without Hyaluronic Acid in Rabbit Osteoarthritis Model.**

Kwon DR1, Park GY2.

**BACKGROUND:** To investigate the effects of AOD9604 intra-articular injections with or without hyaluronic acid (HA) in a collagenase-induced knee osteoarthritis (OA) rabbit model.

**DESIGN:** Mature New Zealand white rabbits (n=32) were randomly administered 2 mg collagenase type II twice in each knee joint. Weekly injections of 0.6 mL saline (Group 1), 6 mg HA (Group 2), 0.25 mg AOD9604 (Group 3), and 0.25 mg AOD9604 with 6 mg HA (Group 4) were administered for 4-7 weeks after the rst intra-articular collagenase injection. The degree of cartilage degeneration was assessed using morphological and histopathological findings, and the degree of lameness was observed at 8 weeks after the first collagenase injection.

**RESULTS:** Mean gross morphological and histopathological scores were significantly higher in Group 1 than in Groups 2, 3, and 4, and the scores were significantly lower in Group 4 than in Groups 2 and 3. The lameness period in Group 4 was significantly shorter than those in Groups 1, 2, and 3. The lameness period in Group 1 was significantly longer than those in Groups 2 and 3.

**CONCLUSION:** Intra-articular AOD9604 injections using ultrasound guidance enhanced cartilage regeneration, and combined AOD9604 and HA injections were more effective than HA or AOD9604 injections alone in the collagenase-induced knee OA rabbit model.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.

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AOD 9604 is a modified form of amino acids 176-191 of the GH polypeptide. Investigators at Monash University discovered that the fat-reducing effects of GH appear to be controlled by a small region near one end of the GH molecule. This region, which consists of amino acids 176-191, is less than 10% of the total size of the GH Molecule and appears to have no effects on growth or insulin resistance.

This hypothesis was proven in animals to a tremendous degree with specimen losing a significant amount of fat mass. However, in phase three clinical trials the peptide didn’t meet its confidence interval. Instead, it is now being studied for its effect on bone and cartilage.

AOD 9604 possesses many other regenerative properties associated with growth hormone. Currently trials are underway to show the application of AOD 9604 in osteoarthritis, Hypercholesterolemia, bone and cartilage repair. AOD 9604 has an excellent safety profile, recently obtaining Human GRAS status in the USA.

PROTOCOL

Content & Potency: **Transdermal**: 600mcg/ml transdermal cream provided in a 30ml transdermal applicator. **Injectable**: 1200mcg/ml subcutaneous injectable provided in a 5ml vial.

Suggested dosage: **Transdermal**: apply 1.0ml (4 clicks) to inner forearms nightly before bed. **Injectable**: inject 0.25ml subcutaneously once daily for 20 days.

CLINICAL RESEARCH

Safety and Tolerability of the Hexadecapeptide AOD 9604 in Humans

Heike Stier, Evert Vos, David Kenley

Background: The human growth hormone (hGH) has fat loss properties making it a potential candidate to treat obesity. AOD 9604 is a peptide fragment of the C-terminus of hGH (Tyr-hGH177-191), which harbors the fat reducing activity of hGH, without its negative effects. In this paper the safety data of AOD 9604 obtained in clinical trials are summarized.

Methods: Six randomized, double-blind, placebo-controlled trials were performed with AOD 9604. Special focus was given to undesired effects associated with hGH treatment: increases in IGF-1 levels, insulin resistance, and impaired glucose tolerance. Blood samples were analyzed for presence of antiAOD 9604 antibodies to exclude immunogenicity.

Results: AOD 9604 had no effect on serum IGF-1 levels, which confirms the hypothesis that AOD 9604 does not act via IGF-1. Results of oral glucose tolerance test demonstrated that, in contrast with hGH, AOD 9604 has no negative effect on carbohydrate metabolism. There were no anti-AOD 9604 antibodies detected in any of the patients selected for antibody assay. In none of the studies did a withdrawal or serious adverse event occur related to intake of AOD 9604.

Conclusion: AOD 9604 displayed a very good safety and tolerability profile indistinguishable from placebo. AOD 9604 did not result in any of the adverse effects associated with full-length hGH treatment.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Pentadecapeptide BPC 157, composed of 15 amino acids, is a partial sequence of body protection compound (BPC) that is discovered in and isolated from human gastric juice. Experimentally it has been demonstrated to accelerate the healing of many different wounds, including tendon-to-bone healing and superior healing of damaged ligaments.

Additionally, BPC 157 has shown to protect organs and aids in the prevention of gastric ulcers. BPC-157 acts systemically in the digestive tract to combat leaky gut, IBS, gastro-intestinal cramps, and Crohn’s disease.

This peptide has been know to exhibit analgesic characteristics. Those who suffer from discomfort due to muscle sprains, tears and damage may benefit from treatment with this peptide. It can also help to aid skin burns at a faster rate by increasing blood flow to damaged tissues.

PROTOCOL

Suggested dosage: Inject 0.15ml injected subcutaneously every day for 30 days.
Oral option: 30 capsules at 500mcg – Take one capsule by mouth once daily for 30 days.

CLINICAL RESEARCH

The Promoting effect of Pentadecapeptide BPC 157 on tendon healing involves tendon outgrowth, cell survival, and cell migration Chung-Hsun Chang, Wen-Chung Tsai Miao-Sui Lin, Ya-Hui Hsu, and Jong-Hwei Su Pang

Many growth factors such as epidermal growth factor (EGF), transforming growth factor-(TGF-), and bone morphogenetic proteins (BMPs) have been used to improve the healing of torn tendon in the lab (2, 31). However, the short duration of these easily digested growth factors hampers their clinical usage. Gastric pentadecapeptide BPC 157 is a partial sequence of human gastric protein BPC, which has been discovered in and isolated from gastric juice (5). It is highly stable and resistant to hydrolysis or enzyme digestion, even in the gastric juice. Besides, it is easily dissolved in water and needs no carrier for its application. Experimentally it was demonstrated to enhance the healing of different wounds, such asgastric ulcer (19, 32), skin (4, 15), cornea (13), muscle (28), colon-colon anastomosis (22), colocolutaneous fistula (11), and segmental bone defect (21). It was also found to accelerate the healing of transected rat Achilles tendon (12, 29) and medial collateral ligament of knee (8). Currently it is in clinical trial for treating inflammatory bowel disease.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

CJC 1295 stimulates growth hormone secretion and will keep a steady increase of HGH and IGF-1 with no increase in prolactin, leading to fat loss, and increased protein synthesis thereby promoting growth.

CJC 1295 is a tetrasubstituted 29-amino acid peptide hormone, primarily functioning as a growth hormone releasing hormone (GHRH) analog. CJC 1295 outperforms the older and outdated GHRH, Sermorelin. The half-life of Sermorelin ranges from 8-12 minutes, whereas the half-life of JJC 1295 extends to 30 minutes. Sermorelin’s efficacy decreases with time and the body produces antibodies to Sermorelin, bioconjugate with serum albumin, thus increasing its half-life and potential therapeutic window. It accomplishes this by using protecting groups around the amino acids of GHRH typically susceptible to enzymatic degradation, thus increasing the half-life. Consequently CJC 129 without DAC is designed to provide a GHRH-like stimulation around the clock with increased amplitude and longer stimulation, (28 minutes instead of 8-12 of sermorelin), maintaining the natural pulsatile stimulation of the pituitary without decreasing secretion as observed in CJC with DAC.

PROTOCOL

Content & Potency: 2000mcg/ml subcutaneous injection provided in a 2ml vial.
Suggested dosage: Inject 0.10ml subcutaneously 5 out of 7 nights of the week before bedtime on an empty stomach.

***We suggest using the CJC 1295 in combination with Ipamorelin as it provides a synergistic effect, generating five times the benefits of using the CJC 1295 or Ipamorelin alone. The combination allows for maximized release of GH because the CJC 1295 and Ipamorelin have different mechanisms of action and work on different receptors (GHRH-R & Ghrelin-R).
Prolonged Stimulation of Growth Hormone (GH) and Insulin-Like Growth Factor I Secretion by CJC 1295, a Long-Acting Analog of GH-Releasing Hormone, in Healthy Adults

Sam L. Teichman, Ann Neale, Betty Lawrence, Catherine Gagnon, Jean-Paul Castaigne, and Lawrence A. Frohman.

WinPharm Associates (S.L.T., A.N.), Alamo, California 94507; ConjuChem, Inc. (B.L., C.G., J.-P.C.), Montréal, Québec, Canada; and Section of Endocrinology, Department of Medicine, University of Illinois (L.A.F.), Chicago, Illinois 60612

Context: Therapeutic use of GHRH to enhance GH secretion is limited by its short duration of action.

Objective: The objective of this study was to examine the pharmacokinetic profile, pharmacodynamic effects, and safety of CJC 1295, a long-acting GHRH analog.

Design: The study design was two randomized, placebo-controlled, double blind, ascending dose trials with durations of 28 and 49 d.

Setting: The study was performed at two investigational sites.

Participants: Healthy subjects, ages 21–61 yr, were studied.

Interventions: CJC 1295 or placebo was administered sc in one of four ascending single doses in the first study and in two or three weekly or biweekly doses in the second study.

Main Outcome Measures: The main outcome measures were peak concentrations and area under the curve of GH and IGF-I; standard pharmacokinetic parameters were used for CJC 1295.

Results: After a single injection of CJC 1295, there were does dependent increase in mean plasma GH concentrations by 2- to 10-fold for 6 d or more and in mean plasma IGF-I concentrations by 1.5- to 3-fold for 9-11 d. The estimated half-life of CJC 1295 was 5.8-8.1 d. After multiple CJC 1295 doses, mean IGF-I levels remained above baseline for up to 28 d. No serious adverse reactions were reported.

Conclusions: Subcutaneous administration of CJC 1295 resulted in sustained, dose-dependent increases in GH and IGF-I levels in healthy adults and was safe and relatively well tolerated, particularly at doses of 30 or 60 ug/kg. There was evidence of a cumulative effect after multiple doses. These data support the potential utility of CJC 1295 as a therapeutic agent.

(J Clin Endocrinol Metab 91:799–805, 2006)

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Dihexa is a peptide variant derived from angiotensin IV which has been found to potently improve cognitive function in animal models of disease such as Alzheimer’s. Angiotensin IV is a derivative of the potent vasoconstrictor angiotensin II and has been shown to enhance acquisition, consolidation and recall of learning and memory in animal models when administered centrally or peripherally. In an assay of neurotrophic activity, Dihexa was found to be seven orders of magnitude more potent than BDNF. It could possibly help in the repair of the brain and nerves in neurological disease.

PROTOCOL

Content & Potency: 20mg/ml transdermal cream provided in a 30ml transdermal applicator.
Suggested dosage: Apply 0.5-1.0ml (2-4 clicks) to inner forearms once daily, rub in until absorbed.

CLINICAL RESEARCH

The Procognitive and Synaptogenic Effects of Angiotensin IV–Derived Peptides Are Dependent on Activation of the Hepatocyte Growth Factor/c-Met System

A subset of angiotensin IV (AngIV)–related molecules are known to possess procognitive/antidementia properties and have been considered as templates for potential therapeutics. However, this potential has not been realized because of two factors: 1) a lack of blood-brain barrier–penetrant analogs, and 2) the absence of a validated mechanism of action. The pharmacokinetic barrier has recently been overcome with the synthesis of the orally active, blood-brain barrier–permeable analog N-hexanoic-tyrosine-isoleucine-α-aminohexanoic amide (dihexa). Therefore, the goal of this study was to elucidate the mechanism that underlies dihexa’s procognitive activity. Here, we demonstrate that dihexa binds with high affinity to hepatocyte growth factor (HGF) and both dihexa and its parent compound Norleucine 1-AngIV (Nle1-AngIV) induce c-Met phosphorylation in the presence of subthreshold concentrations of HGF and augment HGF-dependent cell scattering. Further, dihexa and Nle1-AngIV induce hippocampal spinogenesis and synaptogenesis similar to HGF itself. These actions were inhibited by an HGF antagonist and a short hairpin RNA directed at c-Met. Most importantly, the procognitive/antidementia capacity of orally delivered dihexa was blocked by an HGF antagonist delivered intracerebroventricularly as measured using the Morris water maze task of spatial learning.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DSIP is a well-known neuromodulator and natural somnogenic nonapeptide with many other physiological functions. It is typically found in the brain and easily passes the blood-brain barrier. It is mainly prescribed for the treatment of pain condition, alcohol and opioid withdrawal, CRH and stress related symptoms, low testosterone (via stimulation of LH), and even sometimes as an antioxidant and anti-oncogenic protein.

It has been discovered and heavily studied for over 40 years, yet, the mechanism of action is still complex and not well organized. The results of studies of DSIP and its analogues over a period of 30 years since its discovery enable one to state with confidence that DSIP is a unique member of the family of peptide neuromodulators. It exhibits a pronounced stress protective action and decreases stress-induced metabolic and functional disorders in human and animal organisms exposed to a variety of stresses. Some of the effects of the peptide are accomplished through the modulating action on central regulatory processes, owing to the systemic antioxidant action, the modulating influence on the activity of GABAergic, glutamatergic, and other neuronal systems. It also works on the expression of early response genes in brain structures, and on the activity of biosynthetic and proteolytic processes. DSIP has traditionally been dosed as an IV infusion, however, it can be given subcutaneously as well. Traditional doses have been 100mcg.

Often prescribed for: Pain, to help improve sleep, and to stimulate testosterone levels via LH release.

PROTOCOL

Content & Potency: 1000mcg/ml subcutaneous injectable provided in a 3ml vial. Suggested dosage: Inject 0.1ml subcutaneously once daily at bedtime.

CLINICAL RESEARCH

In several species DSIP at low doses has been shown to promote sleep. Although its physiological role remains to be clarified, DSIP illustrates several concepts applicable to other brain peptides. These include the bell-shaped dose-response curve, central effects after peripheral administration, a delayed and prolonged time course, and some penetration of the blood-brain barrier in essentially intact form. Concepts applicable to one neuropeptide, therefore, appear to be applicable to others. In this article Abba Kastin and colleagues review the known effects of DSIP and argue that more work needs to be carried out before it can be labelled functionally.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
**DESCRIPTION**

Enclomiphene is in the process of treating male hypogonadism (lower function of the reproductive organs) and is a single isomer with pure estrogen antagonism. Enclomiphene is a non-steroidal selective estrogen receptor modulator (SERM) and acts by increasing gonadotropin secretion and gonadal production of testosterone. Enclomiphene has the potential to help the reproductive status in men and improve metabolic profiles.

**PROTOCOL**

Content & Potency: 25mg capsules provided in a quantity of 30.
Suggested dosage: Take one capsule by mouth once daily.

**CLINICAL RESEARCH**

Enclomiphene citrate stimulates testosterone production while preventing oligospermia: a randomized phase II clinical trial comparing topical testosterone.


Objective: To determine the effect of enclomiphene citrate in men with secondary hypogonadism.

Methods: A randomized phase IIIB study enrolled 124 men with a morning serum T level of <250 ng/dL on 2 occasions. Subjects were randomized to one of two doses of enclomiphene citrate (12.5-mg or 25-mg), 1% topical testosterone, or placebo. Hormone levels of LH, FSH, and T and semen level were measured before, during and after 3 months of treatment.

Results: A total of 113 men received 3 months of treatment, and 73 completed the study and provided both baseline and at least 1 semen sample at the end of the study. All 3 active treatment groups showed significantly increased in total testosterone level from baseline compared with placebo, with no statistically significant difference in testosterone levels found between the active treatment groups compared with placebo.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Epithalon (also known as Epitalon or Epithalone) is the synthetic version of the polypeptide Epithalamin which is naturally produced in humans. The pineal peptide preparation is secreted in the epithalamium-epiphyseal region of the brain. Its more prominent tasks are: to regulate metabolism in the epiphysis, increase the sensitivity of hypothalamus to its natural hormonal influences, normalize the function of the anterior pituitary, regulate the levels of gonadotropins and melatonin in the body. Epithalamin increases a person's resistance to emotional stress and also acts as an antioxidant. It is a bio-regulator for the endocrine system, especially for the pineal gland, and has been shown to lengthen telomeres in human cells. The mechanisms in Epitalon are a lot more complex than just activating telomerase. It reduces lipid oxidation and ROS, along with normalizing T cell function. It seems to normalize cholesterol and uric acid, along with prolactin levels. It has shown promise in restoring pancreatic hormone function. Additionally, it restored and normalized melatonin levels in older patients who have lost some pineal function due to aging.

PROTOCOL

Content & Potency: 3000mcg/ml subcutaneous injection provided in a 5ml vial. Suggested dosage: Inject 0.1ml injected subcutaneously every morning.

CLINICAL RESEARCH

Peptide Geroprotector from the Pituitary Gland Inhibits Rapid Aging of Elderly People: Results of 15-Year Follow-Up

O. V. Korkushko, V. Kh. Khavinson*, V. B. Shatilo, and I. A. Antonyk-Sheglova

The paper presents the results of randomized comparative study of the efficiency of peptide geroprotector from the pituitary gland in elderly patients with rapidly aging cardiovascular system. Over three years 39 coronary patients received, in addition to basic therapy, regular courses of epithalamin (peptide drug), while 40 coronary patients (control group) received basic therapy alone. Long-term treatment with epithalamin (6 courses over 3 years) decelerated aging of the cardiovascular system, prevented age-associated impairment of physical endurance, normalized circadian rhythm of melatonin production and carbohydrate and lipid metabolism. A significantly lower mortality in the group of patients treated with epithalamin in parallel with basic therapy also indicated a geroprotective effect of the peptide preparation from the pineal gland.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
GHK-Cu is a naturally occurring copper complex that was first identified in human plasma, but has hence been found in multiple locations such as saliva and urine. Copper peptides are small, naturally occurring protein fragments that have high affinity for copper ions, which are critical to normal body function. GHK-Cu has a variety of roles in the human body including, but not limited to, promoting activation of wound healing, attracting immune cells, antioxidant and anti-inflammatory effects, stimulating collagen and glycosaminoglycan synthesis in skin fibroblasts, and promoting blood vessel growth. There has been evidence that has shown that it acts as a feedback signal that is generated after tissue injury. First, it seems to act as a potent protector of tissue and anti-inflammatory agent that controls the oxidative damage that occurs post-tissue injury. Further, it then plays a big role in signaling tissue remodeling which removes damaged/scarred tissue and generates new, healthy tissue. However, these positive effects decline with age because the concentration of GHK-Cu in the body decreases with age. Thus, there is an increase in inflammation, cancerous activity, and tissue destruction.

**PROTOCOL**

**Content & Potency:**
- **Injectable:** 10mg/ml subcutaneous injection provided in a 5ml vial.
- **Transdermal:** 5mg/ml (5%) topical foam provided in a 50ml foaming applicator.

**Suggested dosage:**
- **Injectable:** Inject 0.2ml subcutaneously once daily.
- **Transdermal:** Apply 1ml (2 pumps) to scalp once daily at night.

**CLINICAL RESEARCH**

GHK Peptide as a Natural Modulator of Multiple Cellular Pathways in Skin Regeneration

GHK (glycyl-L-histidyl-L-lysine) is present in human plasma, saliva, and urine but declines with age. It is proposed that GHK functions as a complex with copper 2+ which accelerates wound healing and skin repair. GHK stimulates both synthesis and breakdown of collagen and glycosaminoglycans and modulates the activity of both metalloproteinases and their inhibitors. It stimulates collagen, dermattan sulfate, chondroitin sulfate, and the small proteoglycan, decorin. It also restores replicative vitality to fibroblasts after radiation therapy. The molecule attracts immune and endothelial cells to the site of an injury. It accelerates wound-healing of the skin, hair follicles, gastrointestinal tract, boney tissue, and foot pads of dogs. It also induces systemic wound healing in rats, mice, and pigs. In cosmetic products, it has been found to tighten loose skin and improve elasticity, skin density, and firmness, reduce fine lines and wrinkles, reduce photodamage, and hyperpigmentation, and increase keratinocyte proliferation. GHK has been proposed as a therapeutic agent for skin inflammation, chronic obstructive pulmonary disease, and metastatic colon cancer. It is capable of up- and downregulating at least 4,000 human genes, essentially resetting DNA to a healthier state. The present review revisits GHK’s role in skin regeneration in the light of recent discoveries.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

IGF-1 is a small peptide consisting of 70 amino acids with a molecular weight of 7649 Da. IGF-1 has an A and B chain connected by disulphide bonds, like insulin, which is how it gets its name. The structural similarity to insulin explains the ability of IGF-1 to bind (with low affinity) to the insulin receptor. IGF-1 is secreted by many tissues and the secretory site seems to determine its actions. Most IGF-1 is secreted by the liver and is transported to other tissues, acting as an endocrine hormone. IGF-1 is also secreted by other tissues, including cartilaginous cells, and acts locally as a paracrine hormone.

Most of the IGF-1 produced by the liver is secreted for its proliferative and growth effects. Lower IGF-1 and growth hormone are often associated with excess body fat. IGF-1 and other proteins in the IGF family are growth factors that stimulate the proliferation and survival of various cell types including muscle, bone, and cartilage tissue. IGF-1 plays an important role in childhood growth and continues to have anabolic effects in adults. A synthetic analog of IGF-1, mecasermin is commercially available and is used for the treatment of growth failure. Therapeutic administration of IGF-1 is associated with reversing insulin sensitivity, reducing weight and increasing metabolic expenditure as well potential reversal of degeneration of spinal cord motor neuron axons in certain peripheral neuropathies.

IGF-1 LR3 has a modified amino acid sequence compared to biological IGF-1. It has an additionally arginine at amino acid position 2. By making this change, it gives the molecule higher potency and a much longer half-life. For this reason it is commonly used as long acting version for the same therapeutic reasons as the IGF-1.

PROTOCOL

Content & Potency: 620mcg/ml subcutaneous injectable provided in two 6.2ml vials.
Suggested dosage: Inject 0.4ml subcutaneously once daily.
**CLINICAL RESEARCH**

**Effects of human growth hormone, insulin-like growth factor I, and diet and exercise on body composition of obese postmenopausal women.**

*Thompson JL, Buttereld GE, Gylfadottir UK, Yesavage J, Marcus R, Hintz RL, Pearman A, Homan AR.*

To determine the effects of GH and insulin-like growth factor I (IGF-I) administration, diet, and exercise on weight loss, body composition, basal metabolic rate (BMR), muscle strength, and psychological status, 33 moderately obese postmenopausal women (67.1 +/- 5.2 yr) participated in a 12-week randomized, double blind study. Participants were placed on a diet that provided 500 Cal/day less than that needed for weight maintenance, and they walked 3 days and strength trained 2 days each week. Subjects also self-injected GH (0.025 mg/kg BW.day), IGF-I (0.015 mg/kg BW.day), a combination of these doses of GH and IGF-I, or placebo (P). Twenty-eight women completed the study, as ve subjects dropped out due to intolerable side-effects (e.g. edema). Weight loss occurred in all groups, with the largest decrease occurring in the **GH plus IGF-I** group (5.6 +/- 1.4 kg). Fat mass significantly decreased in all groups, with the largest losses observed in GH and GH plus IGF-I groups (6.3 +/- 1.8 and 8.4 +/- 2.8 kg, respectively). Despite weight loss, BMR was maintained in all groups. Muscle strength increased with training for all groups, and depression and anxiety scores decreased in groups receiving IGF-I. These data show that obese postmenopausal women can lose weight and fat without compromising fat free mass, BMR, or gains in muscle strength, and that GH and IGF-I given together may enhance fat loss over either given alone.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Ipamorelin is a selective GH-Secretagogue and ghrelin receptor agonist. The potency of ghrelin stimulation can be compared to GHRP6 with less appetite stimulation properties. However, unlike other GH-Secretagogues this pentapeptide doesn’t release the same volumes of cortisol, acetylcholine, prolactin and aldosterone. It is for this reason Ipamorelin has been considered the first selective GH Secretagogue.

PROTOCOL

Content & Potency: 2000mcg/ml subcutaneous injectable provided in a 5ml vial.

Suggested dosage: Inject 0.10ml subcutaneously once daily 5 out of 7 days of the week.

***We suggest using the Ipamorelin in combination with CJC 1295 as it provides a synergistic effect, generating five times the benefits of using the CJC 1295 or Ipamorelin alone. The combination allows for maximized release of GH because the CJC 1295 and Ipamorelin have different mechanisms of action and work on different receptors (GHRH-R & Ghrelin-R).

CLINICAL RESEARCH

Pharmacokinetic-pharmacodynamic modeling of ipamorelin, a growth hormone releasing peptide, in human volunteers.

Gobburu JV, Agersø H, Jusko WJ, Ynddal L. Source: Department of Pharmaceutics, School of Pharmacy, State University of New York at Buffalo, US

Purpose: To examine the pharmacokinetics (PK) and pharmacodynamics (PD) of ipamorelin, a growth hormone (GH) releasing peptide, in healthy volunteers.

Methods: A trial was conducted with a dose escalation design comprising 5 different infusion rates (4.21, 14.02, 42.13, 84.27 and 140.45 nmol/kg over 15 minutes) with eight healthy male subjects at each dose level. Concentrations of ipamorelin and growth hormone were measured.

Results: The PK parameters showed dose-proportionality, with a short terminal half-life of 2 hours, a clearance of 0.078 L/h/kg and a volume of distribution at steady-state of 0.22 L/kg. The time course of GH stimulation by ipamorelin showed a single episode of GH release with a peak at 0.67 hours and an exponential decline to negligible GH concentration at all doses. The ipamorelin-GH concentration relationship was characterized using an indirect response model and population fitting. The model employed a zero-order GH release rate over a finite duration of time to describe the episodic release of GH. Ipamorelin induces the release of GH at all dose levels with the concentration (SC50) required for half-maximal GH stimulation of 214 nmol/L and a maximal GH production rate of 694 mIU/L/h. The interindividual variability of the PD parameters was larger than that of the PK parameters.

Conclusions: The proposed PK/PD model provides a useful characterization of ipamorelin disposition and GH responses across a range of doses.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

iRGD is a cyclic peptide that binds to integrins that are expressed on tumor endothelial cells. Upon binding, a protease cleavage event is activated. When this event is activated the peptide is then able to bind neuropilin-1, activating an endocytotic/exocytotic transport pathway. As a result of this, it is able to hone to tumor cells and make them permeable to transport of many types of cancer therapies. This makes traditional cancer therapies better and less toxic. One study showed that doxorubicin, liposomal doxorubicin, Herceptin trastuzumab or Abraxane nab-paclitaxel had greater drug accumulation in the tumor by up to 40-fold than mice injected with one of the drugs alone. They equaled greater reductions in tumor growth. In all, the drug-peptide combination was as effective as threefold higher doses of drug alone.

PROTOCOL

Content & Potency: 2.5mg/ml subcutaneous injection provided in a 10ml vial.
Suggested dosage: 40mcg/kg subcutaneously once daily in combination with other Cancer treatment.

CLINICAL RESEARCH

Co-administration of a Tumor-Penetrating Peptide Enhances the Efficacy of Cancer Drugs

Poor penetration of anti-cancer drugs into tumors can be an important factor limiting their efficacy. Studying mouse tumor models, we show that a previously characterized tumor-penetrating peptide, iRGD (CRGDK/RGPD/EC), increased vascular and tissue permeability in a tumor-specific and neuropilin-1-dependent manner, allowing co-administered drugs to penetrate into extravascular tumor tissue. Importantly, this effect did not require the drugs to be chemically conjugated to the peptide. Systemic injection with iRGD improved the therapeutic index of drugs of various compositions including a small molecule (doxorubicin), nanoparticles (nab-paclitaxel and doxorubicin liposomes), and a monoclonal antibody (trastuzumab). Thus, co-administration of iRGD may be a valuable way to enhance the efficacy of anti-cancer drugs while reducing their side effects, a primary goal of cancer therapy research.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
KISSPEPTIN-10

DESCRIPTION

Kisspeptins are a group of neuroendocrine peptides that stimulate the release of Gonadotropin Releasing Hormone (GnRH) and is involved in the regulation of developmental sex hormones at the beginning stages of puberty. There have been problems in maturation centered around receptor mutations for kisspeptin. Kisspeptins are encoded by the KISS1 gene, which was originally identified as a human metastasis suppressor gene for melanoma and breast cancer. Kisspeptins have shown therapeutic benefits regarding the upregulation of the endogenous production of Luteinizing Hormone (LH) and Follicular Stimulating Hormone (FSH) through the HPA axis. Thus, it can stimulate Leydig cells to produce testosterone without the result of hypogonadism shown with exogenous testosterone usage.

The expression of Kiss1 has also been altered in other situations of energy imbalance such as obesity and diabetes. It has also been shown to reverse the effects of hypogonadotropic hypogonadism. It also shows other physiologic effects such as helping with egg implantation and maturation in reproduction, as well as the prevention of ectopic pregnancy. Further, in the kidneys it has been shown to increase aldosterone production as well as pregnenolone breakdown and kisspeptin – angiotensin2 production.

PROTOCOL

Content & Potency: 100mcg/ml subcutaneous injection provided in a 5ml vial.
Suggested dosage: Inject 0.10ml subcutaneously once daily.
**KISSPEPTIN-10**

**Purity:** >98% (HPLC on request)

**Molecular Formula:** C_{63}H_{83}N_{17}O_{14}

**Molecular Weight:** 1302.462 g/mol

**Sequence:** Tyr-Asn-Trp-Asn-Ser-Ph-e-Gly-Leu-Arg-Phe-NH

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**CLINICAL RESEARCH**

**Kisspeptin-10 Is a Potent Stimulator of LH and Increases Pulse Frequency in Men**


**Author information, Article notes, Copyright and License information, Disclaimer**

**Objective:** We investigated our hypothesis that kisspeptin-10 increases GnRH and thus LH pulse frequency.

**Design and Participants:** The dose response of kisspeptin-10 was investigated by administering iv bolus doses (0.01–3.0 μg/kg) and vehicle to healthy men. Effects on LH pulse frequency and size were determined by deconvolution analysis during infusion of kisspeptin-10 for up to 22.5 h.

**Results:** Intravenous bolus kisspeptin-10 resulted in a rapid and dose-dependent rise in serum LH concentration, with maximal stimulation at 1 μg/kg (4.1 ± 0.4 to 12.4 ± 1.7 IU/liter at 30 min, P < 0.001, n = 6). Administration of 3 μg/kg elicited a reduced response vs. 1 μg/kg (P < 0.05). Infusion of kisspeptin-10 at 4 μg/kg · h for 22.5 h elicited an increase in LH from a mean of 5.4 ± 0.7 to 20.8 ± 4.9 IU/liter (n = 4; P < 0.05) and serum testosterone increased from 16.6 ± 2.4 to 24.0 ± 2.5 nmol/liter (P < 0.001). LH pulses were obscured at this high rate of secretion, but a lower dose infusion of kisspeptin-10 (1.5 μg/kg · h) increased mean LH from 5.2 ± 0.8 to 14.1 ± 1.7 IU/liter (n = 4; P < 0.01) and increased LH pulse frequency from 0.7 ± 0.1 to 1.0 ± 0.2 pulses/h (P < 0.05) and secretory burst mass from 3.9 ± 0.4 to 12.8 ± 2.6 IU/liter (P < 0.05).

**Conclusions:** Kisspeptin-10 boluses potently evoke LH secretion in men, and continuous infusion increases testosterone, LH pulse frequency, and pulse size. Kisspeptin analogues have therapeutic potential as regulators of LH and thus testosterone secretion.

**A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.**
DESCRIPTION

LL-37 is an antimicrobial peptide which belongs to the cathelicidin family of AMPs (antimicrobial peptides). LL-37, like cathelicidins, are stored in neutrophil granules as inactive precursors and are released as mature peptides when neutrophils are stimulated. LL-37 is expressed in various cells and tissues such as circulating neutrophils and myeloid bone marrow cells, epithelial cells of the skin, and is also expressed in the gastrointestinal tract, as well as in the epididymis and lungs. Moreover, production of LL-37 in macrophages is stimulated by vitamin D released by sunlight through the skin. LL-37 plays an important role in the first line of defense against infection and systemic invasion of pathogens at sites of inflammation and wound. It is cytotoxic to both bacterial and normal eukaryotic cells and is significantly resistant to proteolytic degradation in solution. LL-37 shows a broad spectrum of antimicrobial activity against bacteria, enveloped viruses, and fungi. It has also demonstrated success in helping promote wound healing and it may play a negative role in atopic dermatitis and psoriasis.

PROTOCOL

Content & Potency: 2000mcg/ml subcutaneous injection provided in a 5ml vial.
Suggested dosage: Varies with indication and patient.

CLINICAL RESEARCH

Membrane Core-Specific Antimicrobial Action of Cathelicidin LL-37 Peptide Switches Between Pore and Nanofibre Formation

Membrane-disrupting antimicrobial peptides provide broad-spectrum defence against localized bacterial invasion in a range of hosts including humans. The most generally held consensus is that targeting to pathogens is based on interactions with the head groups of membrane lipids. Here we show that the action of LL-37, a human antimicrobial peptide switches the mode of action based on the structure of the alkyl chains, and not the head groups of the membrane forming lipids. We demonstrate that LL-37 exhibits two distinct interaction pathways: pore formation in bilayers of unsaturated phospholipids and membrane modulation with saturated phospholipids. Uniquely, the membrane modulation yields helical-rich fibrous peptide-lipid superstructures. Our results point at alternative design strategies for peptide antimicrobials.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
Melanotan I and Melanotan II are both analogs of the peptide hormone alphamelanocyte stimulating hormone (α-MSH) that induces skin tanning. Like its predecessor, Melanotan I, MT 2 plays a role in stimulating melanogenesis and thus provides a protective mechanism against UV rays since under its actions melanocytes are able to increase production and secretion of the hormone melanin. Scientists have also noticed that MT 2 had a positive effect on libido due to its aphrodisiac properties. Additionally, MT 2 exhibits a mild positive fat-mobilizing effect. Melanotan I is an FDA approved drug under the brand name Scenesse. Scenesse is most commonly used to treat patients that have an intolerance to light.

**PROTOCOL**

**Content & Potency:** 2000mcg/ml subcutaneous injection provided in a 5ml vial.

**Suggested dosage:** Inject 0.15ml once daily for 1 - 2 weeks then 0.25mL twice weekly for maintenance.

**CLINICAL RESEARCH**

Evaluation of melanotan-II, a superpotent cyclic melanotropic peptide in a pilot phase-I clinical study.

*Dorr RT, Lines R, Levine N, Brooks C, Xiang L, Hruby VJ, Hadley ME. Source: College of Medicine, Pharmacology Department, University of Arizona, Tucson, USA.*

**Abstract:** A pilot phase I study was conducted with a cyclic heptapeptide analog of alpha-melanocyte stimulating hormone (alpha-MSH). The lactam-bridged molecule, called Melanotan-II (MT-II), has the structure Ac-Nle4-Asp5-His6-D-Phe7-Arg8-Trp9-Lys10 alpha-MSH4-10-NH2 (MT-II) and has superpotent melanotropic activity in vitro. A single-blind, alternating day (saline or MT-II), placebo-controlled trial was conducted in 3 normal male volunteers at the starting dose of 0.01 mg/kg of MT-II. Subcutaneous injections of MT-II or saline were given daily (Monday-Friday) for 2 consecutive weeks. Two subjects were escalated by 0.005 mg/kg increments to 0.03 mg/kg and one to 0.025 mg/kg. The 0.03 mg/kg dose produced Grade II somnolence and fatigue in one of two subjects (WHO standards). Mild nausea, not requiring antiemetic treatment, was reported at most MT-II dose levels. A stretching and yawning complex appeared to correlate with the onset of spontaneous, Penile erections which were intermittently experienced for 1-5 hours after MT-II dosing, depending on the MT-II dose. Two subjects had increased pigmentation in the face, upper body and buttock, as measured by quantitative reflectance and by visual perception 1 week after MT-II dosing ended. These results demonstrate that MT-II has tanning activity in humans given only 5 low dose every other day by subcutaneous injection. The recommended single MTII dose for future Phase I studies is 0.025 mg/kg/day.

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*A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.*
DESCRIPTION

MK-677 is a long active orally bioactive agonist of the GHS-R1a. As such, binds to the same receptor that GHRP2, GHRP6, and Ipamorelin also stimulate. Also called Ibutamoren, it has shown to cause a predictable rise in IGF-1 but unlike other GH secretagogues doesn’t help to decrease adipose tissue. It has been shown to increase lean muscle mass and might be a good candidate for sarcopenic patients with low bone mineral density. In order to reduce the negative effect of somatostatin, MK-677 is best taken on an empty stomach with no insulin in the system.

PROTOCOL

Content & Potency: 25mg capsules provided in quantities of 30.
Suggested dosage: Take one capsule by mouth once daily on an empty stomach.

CLINICAL RESEARCH

Effects of an Oral Ghrelin Mimetic on Body Composition and Clinical Outcomes in Healthy Older Adults  A Randomized Trial
Ralf Nass, MD; Suzan S. Pezzoli, BA; Mary Clancy Oliveri, MS; James T. Patrie, MS; Frank E. Harrell Jr., PhD; Jody L. Clasey, PhD; Steven B. Heymsfield, MD; Mark A. Bach, MD; Mary Lee Vance, MD; and Michael O. Thorner, MB, BS, DSc

Background: Growth hormone secretion and muscle mass decline from midpuberty throughout life, culminating in sarcopenia, frailty, decreased function, and loss of independence. The decline of growth hormone in the development of sarcopenia is one of many factors, and its etiologic role needs to be demonstrated.

Objective: To determine whether MK-677, an oral ghrelin mimic, increases growth hormone secretion into the young-adult range without serious adverse effects, prevents the decline of fat-free mass, and decreases abdominal visceral fat in healthy older adults.

Conclusion: Over 12 months, the ghrelin mimetic MK-677 enhanced pulsatile growth hormone secretion, significantly increased fat-free mass, and was generally well tolerated. Long-term functional and, ultimately, pharmacoeconomic, studies in elderly persons are indicated.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
**DESCRIPTION**

MGF is a split variant of IGF-1 but its sequence differs from the systemic IGF-1 produced by the liver. IGF-1 is spliced towards MGF which initiates hypertrophy and repair of local muscle damage. MGF is expressed by mechanically overloaded muscle and is involved in tissue repair and adaptation. It is expressed as a pulse following muscle damage and is involved in the activation of muscle satellite (stem) cells. These donate nuclei to the muscle fibers that are required for repair and for the hypertrophy process, which may have similar regulatory mechanisms. MGF is essential for repair and therefore growth of new cells, similar to IGF-1. If MGF is not PEGylated, the half-life is several minutes therefore PEGylated MGF must be considered during the compounding process to ensure an appropriate half-life, thereby increasing duration of action.

**PROTOCOL**

**Content & Potency:** 2000mcg/ml subcutaneous injection provided in a 5ml vial.

**Suggested dosage:** Inject 0.10ml once daily for 5 out of 7 days of the week (1 month supply).

**CLINICAL RESEARCH**

A.Philippou1, E. Papageorgiou1, G. Bogdanis2, A. Halapas1, A. Sourla3, m. Maridaki, N. Pissimissis Source: Department of Experimental Physiology, Medical School, National and Kapodistrian University of Athens.

**Abstract:** Different insulin-like growth factor-1 (IGF-1) isoforms, namely IGF-1Eb and IGF-1Ec (MGF), have been proposed to have various functions in muscle repair and growth. To gain insight into the potentially differential actions of IGF-1 isoforms in the regulation of muscle regeneration, we assessed the time course of their expressions at both mRNA and protein levels after exercise-induced muscle damage in humans. In addition, we characterized mature IGF-1 and synthetic MGF E peptide signalling in C2C12 myoblast-like cells in vitro. Ten healthy male volunteers were subjected to exercise-induced muscle damage and biopsy samples were taken from the exercised muscles before and 6 h, 2, 5 and 16 days post exercise. Muscle damage was documented by specific functional and biochemical responses post exercise. PCR-based analyses of muscle biopsy samples revealed a rapid and transient up-regulation of MGF mRNA expression which was followed by a prolonged increase of IGF-1Ea and IGF-1Eb mRNA expression (p<0.05). Patterns similar to those for mRNA expression were detected for MGF and IGF-1Ea expression at the protein level. The action of synthetic MGF E peptide differed from that of mature IGF1 since its proliferative effect on C2C12 myoblast-like cells was not blocked by an anti-IGF-1 receptor neutralizing antibody and it did not phosphorylate Akt. Therefore, we conclude that the differential expression profile of IGF-1 isoforms in vivo and the possible IGF-1R- independent MGF E peptide signalling in skeletal muscle-like cells in vitro support the notion that tissue-specific mRNA expression of MGF isoform produces mature IGF-1 and MGF E peptides which possibly act as distinct mitogens in skeletal muscle regeneration.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.

Tailor Made Compounding | Ph: 1 859 887 0013 | admin@tailormadecompounding.com
DESCRIPTION

Pentosan polysulfate is a semi-synthetic polysulfated xylan used for the relief of Osteoarthritis. The mechanism of PPS action in osteoarthritis is multifactorial, with both stimulation of cartilage matrix synthesis and prevention of cartilage breakdown. There are also systemic effects on blood lipid and fibrinolysis that may help clear the subchondral circulation. In one study, after a series of four to six intra-articular PPS injections into knees of human volunteers, there was a significant increase in the size of the synovial fluid hyaluronan without causing any inflammation or bleeding into the joint cavity.

PROTOCOL

Content & Potency: 250mg/ml solution provided in a 10ml vial.
Suggested dosage: Inject 1-2ml directly into the intra-articular space.

CLINICAL RESEARCH

Intra-articular injection pentosanpolysulphate results in increased hyaluronan molecular weight in joint fluid.

The influence of an oversulphated glycosaminoglycan, pentosanpolysulphate, on hyaluronan metabolism of the synovial lining cell was studied in vivo in human volunteers. Significant increases in the mean degree of polymerisation of the hyaluronan chains were observed after a series of four to six intra-articular injections of this glycosaminoglycan. No increases in hyaluronan synthesis rates were observed. Repeated administration of the drug did not cause any inflammation or bleeding in the joint cavity.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Bremelanotide (PT-141) was developed from the peptide hormone Melanotan II. In initial testing, Melanotan II induced darkening of skin pigment, but additionally caused sexual arousal and spontaneous erections as unexpected side effects in nine out of the ten original male volunteer test subjects. Further testing in animals showed Bremelanotide to induce lordosis (a sexual mating behavior) and subsequently tested for its effect in humans. Although, most of the research has been targeted to women with female sexual dysfunction an effective medication in treating sexual dysfunction in both men (erectile dysfunction or impotence) and women (sexual arousal disorder). Unlike Viagra and other related medications, it does not act upon the vascular system, but directly increases sexual desire via the nervous system.

It is estimated that 43% of women (30 million is the US) suffer from sexual dysfunction and 30 million men suffer from ED, with incidence increasing 2-3 fold between ages 40-70. Bremelanotide currently has no contraindications and is 80% effective in people don’t respond to Viagra or Cialis.

PROTOCOL

Content & Potency: 10mg/ml subcutaneous injection provided in a 2ml vial.
Suggested dosage: Inject 0.2mL subcutaneously as needed, 30 minutes prior to sexual activity. The initial dose will establish a time frame for response. Men should start at 0.1ml.

CLINICAL RESEARCH

Melanocortins in the treatment of male and female sexual dysfunction.
Shadiack AM, Sharma SD, Earle DC, Spana C, Hallam TJ.

Abstract: Melanocortinergic agents are currently being investigated for a possible therapeutic role in male and female sexual dysfunction. These investigations were sparked by findings that systemic administration of a synthetic analog of alpha-MSH, MT-II, causes penile erections in a variety of species, including humans. Several other melanocortinergic agents including HP-228, THIQ, and bremelanotide (PT 141) have since been shown to have erectogenic properties thought to be due to binding to melanocortin receptors in the central nervous system, particularly the hypothalamus. Bremelanotide, a nasally administered synthetic peptide, is the only melanocortinergic agent that has been clinically studied in both males and females. Data from Phase II clinical trials of bremelanotide support the use of melanocortin based therapy for erectile dysfunction. Studies using animal models have demonstrated that precopulatory behaviors in female rats analogous to sexual arousal are evoked, and preliminary clinical data also suggest a role in promoting sexual desire and arousal in women. Based on bremelanotide clinical experience, administration of a melanocortin agonist is well tolerated and not associated the hypotension observed with phosphodiesterase-5 inhibitors currently used to treat erectile dysfunction. This review discusses investigations of melanocortin agonists for the treatment of sexual dysfunction with emphasis on proposed sites and mechanisms of action in the central nervous system that appear to be involved in melanocortinergic modulation of sexual function.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION
Selective Androgen Receptor Modulators (SARMs) provide the benefits of traditional anabolic/androgenic steroids such as testosterone (including increased muscle mass, fat loss, and bone density), while having lower unwanted side effects characteristic of oral anabolics (aromatization / increased DHT). By stimulating the androgen receptor, SARMs can provide a similar therapeutic outcome to androgen therapy without any increase in androgen levels. SARMs have the potential to take the place of the androgens, and therefore exert many of the same positive effects on muscle tissue. SARMs can be administered in an injectable dosage form and are absorbed orally with no liver toxicity as with most oral steroids. The anabolic effect has been measured to be roughly the same or greater than testosterone. It has also been shown to produce dose-dependent increases in bone mineral density and mechanical strength, decrease body fat and increase lean body mass.

LGD-4033 is a relatively new SARM on the market. It can be dosed orally at low doses and has a very strong anabolic effect.

PROTOCOL
Content & Potency: 0.5mg capsule provided in a quantity of 30.
Suggested dosage: one capsule once daily for 32 days should be cycled (one month on, one month off).

CLINICAL RESEARCH

Background: Concerns about potential adverse effects of testosterone on the prostate have motivated the development of selective androgen receptor modulators that display tissue-selective activation of androgenic signaling. LGD-4033, a novel nonsteroidal, oral selective androgen receptor modulator, binds androgen receptor with high affinity and selectivity.

Objectives: To evaluate the safety, tolerability, pharmacokinetics, and effects of ascending doses of LGD-4033 administered daily for 21 days on lean body mass, muscle strength, stair-climbing power, and sex hormones.
Methods: In this placebo-controlled study, 76 healthy men (21 – 50 years) were randomized to placebo or 0.1, 0.3, or 1.0 mg LGD-4033 daily for 21 days. Blood counts, chemistries, lipids, prostate-specific antigen, electrocardiogram, hormones, lean and fat mass, and muscle strength were measured during and for 5 weeks after intervention.

Conclusions: LGD-4033 was safe, had favorable pharmacokinetic profile, and increased lean body mass even during this short period without change in prostate-specific antigen. Longer randomized trials should evaluate its efficacy in improving physical function and health outcomes in select populations.

Purity: >98% (HPLC on request)
Molecular Formula: C14H12F6N2O
Molecular Weight: 338.25/mol
Sequence:: Non-Peptide
DESCRIPTION

Selank is another ACTH/MSH-like peptide of the melanocortin class most closely related to the analog tufstin. While traditionally prescribed for anxiety and depression, it has been known to be conductive in many other treatments related to immune modulation, anticoagulation, PTSD, ADHD, and metabolic syndromes.

Selank has pronounced anxiolytic activity and acts as a stable neuropsychotropic, antidepressant, and anti-stress drug that relieves aggression and fear reaction in different animal species. Selank also has a nootropic action, which positively influences the formation of memory and learning processes, and marked immunomodulatory activity. Clinical studies have shown that the effect of selank is similar to that of tranquilizers at low doses, but is not accompanied by the unwanted side effects of benzodiazepine tranquilizers such as amnesia, withdrawal, or dependence. Experiments have also demonstrated the effectiveness of Selank in preventing the accumulation of body fat (i.e., weight gain) with simultaneous activation of the functional state of the anticoagulation system in development of the metabolic syndrome. Furthermore, decreased blood glucose levels have been observed with chronic treatment of this peptide. The peptide Selank, like the drug Semax, induces anticoagulant and hyperglycemia effects possibly due to the presence of the same amino acid sequence, Pro-Gly-Pro, in its structure. Thus, Selank can be used as a broad-spectrum therapeutic agent for the treatment of metabolic syndrome.

Often prescribed for: Anxiolytic, Immune improvement, gastric protection, as a preventative weight gain/metabolic syndrome, and with opioid and alcohol withdrawal/dependence.

PROTOCOL

Content & Potency: 7500mcg/ml provided in a 3ml nasal spray applicator.
Suggested dosage: Instill two sprays intranasally once daily.

CLINICAL RESEARCH

P-1114 - Rapid and Slow Response During Treatment of Generalized Anxiety Disorder with Peptide Anxiolytic Selank

T. Syunyakov, E.S Teleshova, G.G. Neznamov, V.K.Bochkarev

Introduction: Heptapeptide Selank approved for the treatment of Generalized Anxiety Disorder (GAD). Studies revealed that Selank acts as an anxiolytic with stimulatory and cognitive enhancing properties. Though time to treatment response significantly varied in patients and this issue has not been studied.

Objectives: Individual treatment response analysis in Selank-treated patients with GAD.
Aims: To compare clinical state and EEG changes in patients with different time to treatment response to Selank.

Methods: 20 patients aged 24-52 y.o. with GAD according to DSM-IV were included. Selank was administered at the dose 2700 µg/day intranasally. Study utilized valid clinical scales and pharmaco-EEG.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

It is well known that ACTH/MSH-like peptides (melanocortins) exert pleiotropic non-hormonal actions among their larger activities. Melanocortins affect learning processes and exploratory behavior, regeneration and development, nociceptive and inflammatory processes, accelerate nerve regeneration and improve neuromuscular performance. Together these classes of peptides control many behaviors such as regulating attention, processes of learning, and memory formation as a result of their pronounced effect on CNS functions. Heptapeptide SEMAX (MEHFPGP) is the analogue of ACTH (4-10) that has prolonged neurotropic activity and thus is a good candidate for medical therapy. Currently this peptide is successfully used in treatment of patients with pathologies related to brain circulation dysfunction and with different intellectual-amnestic problems of the CNS. Doctors have prescribed it for many conditions like anxiety, memory improvement, ischemic events, stroke, nerve regeneration, ADHD, opioid withdrawal, and even chronic diseases such as ALS, Parkinson’s, and Alzheimer’s. Some doctors use it as a preventative measure to protect against chronic disease and to acutely help improve memory and learning processes. It also has a marked antithrombotic and fibrinolytic effect and a gastric protective effect. It has also been suggested in literature that due to its effect on carboxypeptidase it can also increase physical performance and adaptation capacities in exposure to high intensity exercise. At its higher doses, .5mg/kg can even be analgesic.

Often prescribed for: Anti-Thrombosis, ADHD/Learning, Gastric protection, Physical exertion improvement pain, Metal toxicities.

PROTOCOL

Content & Potency: 7500mcg/ml provided in a 3ml nasal spray applicator.
Suggested dosage: Instill two squirts sprays of 0.10ml intranasally once daily.

CLINICAL RESEARCH

The Nootropic and Analgesic Effects of Semax Given via Different Routes

The heptapeptide Semax (MEHFPGP) is an analog of the fragment ACTH(4–10) with long-lasting actions. The aim of the present work was to study the effects of Semax on learning ability and pain sensitivity in white rats given different doses via the intraperitoneal and intranasal routes. The nootropic effects of Semax were studied in a test based on the acquisition of a conditioned passive avoidance reaction to pain stimulation. Pain sensitivity was assessed in a hindpaw compression test. The results showed that i.p. Semax had nootropic and analgesic actions. Dose-response characteristics were different for these different effects. Intranasal Semax was more effective in improving learning in animals than i.p. Semax but had no effect on pain sensitivity. Our results provide evidence that different mechanisms and brain structures are involved in mediating the nootropic and analgesic effects of Semax.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Tesamorelin is a growth hormone releasing hormone analog that increases IGF-1 levels in men and women, by an average of 181 micrograms/liter. It binds to and stimulates GHRH receptors with similar potency as endogenous GHRH. It has a host of other benefits including nootropic effects and reducing triglycerides.

Tesamorelin has subsequently been shown to decrease carotid intima-media thickness (cIMT), visceral adipose tissue (VAT), and c-reactive protein (CRP). It has not been linked to significantly affect other pituitary hormones and their respective mechanisms in the body. Additionally, it can improve cognitive function for healthy seniors and patients with an increased risk of Alzheimer’s disease, due to mild cognitive impairment.

PROTOCOL

Content & Potency: 1mg lyophilized subcutaneous injectables presented in a quantity of 24 vials with 10ml of sterile water for injection for reconstitution.

Suggested dosage: Reconstitute each vial prior to injection with 0.6ml sterile water for injection, inject 0.5ml subcutaneously before bed 6 out of 7 days 90 minutes after last food intake.

CLINICAL RESEARCH

Effects of a Growth Hormone-Releasing Hormone Analog on Endogenous GH Pulsatility and Insulin Sensitivity in Health Man

Takara L. Stanley, Cindy Y. Chen, Karen L. Branch, Hideo Makimura, and Steven K. Grinspoon Program in Nutritional Metabolism and Neuroendocrine Unit (T.L.S., C.Y.C., H.M., S.K.G.) and the Clinical Research Center (K.L.B.), Massachusetts General Hospital and Harvard Medical School, Boston, Massachusetts 02114

Background: Strategies to augment pulsatile GH may be beneficial in patients with excess visceral adiposity, in whom GH secretion is reduced. The objective of this study was to determine the effects of a novel GHRH (GHRH1–44) analog, tesamorelin, on endogenous GH pulsatility and insulin sensitivity in healthy men.

Methods: Thirteen males (mean age 45 ± 3 yr and body mass index 27.3 ± 1.2 kg/m2) received tesamorelin 2 mg sc once daily for 2 wk, with assessment made at baseline, after 2 wk of treatment, and after 2 wk of withdrawal. The primary end point was change in mean overnight GH as determined by overnight frequent sampling. Secondary end points included insulin-stimulated glucose uptake as measured by euglycemic hyperinsulinemic clamp; IGF-I; and GH secretion parameters, including pulse area, pulse frequency, and basal secretion.

Results: Tesamorelin treatment increased mean overnight GH (change +0.5 ± 0.1 μg/liter, P = 0.004), average log10 GH peak area (change +0.4 ± 0.1 log10 μg/liter, P = 0.001), and basal GH secretion (change +0.008 ± 0.003 μg/liter · min, P = 0.008). IGF-I increased by 181 ± 22 μg/liter (P < 0.0001). Neither fasting glucose (P = 0.93) nor insulin-stimulated glucose uptake (P+ 0.61) was significantly affected by tesamorelin.

Conclusion: Once-daily short-term treatment with a GHRH1–44 analog, tesamorelin, augments basal and pulsatile GH secretion. Moreover, although tesamorelin significantly increase IGF-I, peripheral insulin-stimulated glucose uptake appears to be preserved. (J Clin Endocrinol Metab 96: 150–158, 2011).

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DESCRIPTION

Tesofensine is part of the Phenyltropane family. This drug is used to combat obesity and serve as an appetite suppressant. Tesofensine is serotonin-noradrenaline-dopamine reuptake inhibitor. This medication indirectly stimulates the cholinergic system and showed to be more successful than average weight loss medication.

Tesofensine (TE) increases near transmission of 3 monoaminergic neurotransmitters in the brain. These neurotransmitters are serotonin, norepinephrine, and dopamine which help regulate energy balance and are linked to obesity and depression.

PROTOCOL

Content & Potency: 500mcg capsule provided in a quantity of 30 capsules.
Suggested dosage: Take 1 capsule by mouth once daily in the morning.

CLINICAL RESEARCH

Professor Arne Astrup MD, Professor Sten Madsbad MD, Leif Breum MD, Thomas J Jensen MD, Jens Peter Kroustrup MD, Thomas Meinert Larsen PhD.

Background: To evaluate the efficacy on weight reduction, metabolic parameters and safety of tesofensine versus placebo in obese patients mechanism(s). Finding the reason behind weight reduction by measuring energy expenditure in obese individuals.

Methods: 161 (79%) participants completed the study. After 24 weeks, the mean weight loss produced by diet and placebo was 2.0% (SE 0.60). Tesofensine 0.25 mg, 0.5 mg, and 1.0 mg and diet induced a mean weight loss of 4.5% (0.87), 9.2% (0.91), and 10.6% (0.84), respectively, greater than diet and placebo (p<0.0001)

Results: The results suggest that tesofensine 0.5 mg might have the potential to produce a weight loss twice that of currently approved drugs.

Conclusion: TE has cause an effect on appetite sensations and a slight effect on energy expenditure at night—both effects can contribute to the strong weight-reducing effect of TE.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
**DESCRIPTION**

Tetradecylthioacetic Acid, otherwise known as TTA, is a PPAR-alpha activator. Although similar in structure to an omega-3 fatty acid, it cannot be utilized for energy and thus has no relevant caloric value to humans. PPAR-alpha is a transcription factor and a major regulator of lipid metabolism in the liver. PPAR-alpha is activated under conditions of energy deprivation and is necessary for the process of ketogenesis, a key adaptive response to prolonged fasting. Activation of PPAR-alpha promotes uptake, utilization, and catabolism of fatty acids by upregulation of genes involved in fatty acid transport, fatty acid binding and activation, and peroxisomal and mitochondrial fatty acid β-oxidation. The clearing of fat from the blood causes a drop in lipoproteins and a lowering of LDL cholesterol. TTA has also been shown to decrease blood pressure and exert an mild anti-oxidant effect.

**PROTOCOL**

**Content & Potency:** 200mg capsules provided in quantities of 90 capsules.

**Suggested dosage:** Take 1 capsule by mouth 3 times daily.

**CLINICAL RESEARCH**

Dietary supplementation of tetradecylthioacetic acid increases feed intake but reduces body weight gain and adipose depot sizes in rats fed on high-fat diets.

Despite higher feed intake during the final 2 weeks of the study, rats fed on TTA gained less body weight than lard-fed rats and had markedly decreased subcutaneous, epididymal, perirenal and mesenteric adipose depots. The effects of TTA feeding with reduced body weight gain and energy efficiency (weight gain/feed intake) started between day 10 and 13. Body contents of fat, protein and water were reduced after feeding lard plus TTA, with a stronger decrease in fat relative to protein. Plasma lipids, including Non-Esterified Fatty Acids (NEFA), were significantly reduced, whereas fatty acid β-oxidation in liver and heart was enhanced in lard plus TTA-fed rats. Hepatic UCP3 was expressed ectopically both at protein and mRNA level (>1900-fold), whereas Ucp1 mRNA was increased 30-fold in epididymal and 90-fold in mesenteric fat after lard plus TTA feeding.

**Conclusion:** Our data support the hypothesis that TTA feeding may increase hepatic fatty acid β-oxidation, and thereby reduce the size of adipose tissues. The functional importance of ectopic hepatic UCP3 is unknown but might be associated with enhanced energy expenditure and thus the reduced feed efficiency.
DESCRIPTION

Thymosin is a hormone secreted from the thymus. Its primary function is to stimulate the production of T cells, which are an important part of the immune system. Thymosin also assists in the development of B cells to plasma cells to produce antibodies. The predominant form of Thymosin, Thymosin Beta 4, is a member of a highly conserved family of actin monomer-sequestering proteins. In addition to its role as a major actin-sequestering molecule, Thymosin Beta 4 plays a role in tissue repair. Tβ4 has been found to play an important role in protection, regeneration and remodeling of injured or damaged tissues. The gene for Tβ4 has also been found to be one of the first to be upregulated after injuries. Thymosin Beta 4 is currently being trialed as a potential therapy for HIV, AIDS, and Influenza. Thymosin Beta 4 is most often prescribed for acute injury, surgical repair and for senior athletes. It has most recently been shown to help regrow hair in addition to PRP.

PROTOCOL

Content & Potency: 3000mcg/ml subcutaneous injection provided in a 5ml vial.
Suggested dosage: Inject 0.25ml subcutaneously daily for 20 days.

CLINICAL RESEARCH

Abstract: A cDNA clone encoding human thymosin-beta 4 was isolated from a cDNA library prepared from peripheral blood leukocytes of a patient with acute lymphocytic leukemia. This clone contained the entire coding sequence of 43 amino acid residues of thymosin-beta 4 and had an initiation codon and two termination codons. The amino acid and nucleotide sequences in the coding region were well conserved between rat and human. Nine of 132 nucleotides were different in the coding sequences (93% homology), but the deduced amino acid sequences were identical. No signal peptide was found in the deduced protein sequence. Human thymosin-beta 4 mRNA, approximately 830 nucleotides in length, was about 30 nucleotides larger than rat thymosin-beta 4 mRNA. Expression of the human thymosin-beta 4 gene in various primary myeloid and lymphoid malignant cells and in a few human hemopoietic cell lines was studied. Northern blot analyses of different neoplastic B lymphocytes revealed that steady state levels of thymosin-beta 4 mRNA varied as a function of differentiation stage. Thymosin-beta 4 mRNA levels were decreased in myeloma cells as are class II human leukocyte antigen, Fc receptor, and complement receptor, suggesting a relationship between thymosin-beta 4 and the immune response. Thymosin-beta 4 mRNA was more highly expressed in mature granulocytes than in immature elastic cells. Treatment of THP-1 cells, a human monocyct cell line, with recombinant human interferon-lambda reduced the levels of thymosin-beta 4 mRNA. Its level decreased after differentiation of THP-1 cells into la+ macrophages, but increased after differentiation of HL-60 cells into la- macrophages. The pattern of thymosin-beta 4 gene expression suggests that it may play a fundamental role in the host defense mechanism.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.
DESCRIPTION

Vasoactive intestinal polypeptide (VIP) is a naturally produced neuropeptide that functions as a neuromodulator and neurotransmitter. It is a potent vasodilator, regulates smooth muscle activity, epithelial cell secretion, and blood flow in the gastrointestinal tract. As a chemical messenger, it functions as a neurohormone and paracrine mediator. Therapeutically, it is often dosed nasally in patients with mold toxicity and other biotoxin illnesses. In these patients, exogenous administration can help support healthy hormone levels, works to limit inflammation, regulates the immune system, and help in the healing activity of the brain.

PROTOCOL

Content & Potency: 500mcg/ml provided in a 12 ml nasal spray applicator.
Suggested dosage: Instill 50mcg intranasally in alternating nostrils up to 4 times daily.

CLINICAL RESEARCH

Vasoactive intestinal polypeptide (VIP) corrects chronic inflammatory response syndrome (CIRS) acquired following exposure to water-damaged buildings

Exposure in water-damaged buildings (WDB) to airborne bioaerosols including metabolic products of toxigenic fungi, bacteria and actinomycetes; and inflammagens, can lead to a persistent innate immune inflammatory illness. This illness, termed a chronic inflammatory response syndrome (CIRS-WDB), is systemic with symptoms acquired from multiple organ systems. Treatment of CIRS-WDB has progressed rapidly as a better understanding of the inflammatory pathophysiology has led to targeted, sequential therapies. The fundamental basis of uncontrolled innate immune responses, the humoral deficiency of regulatory neuropeptides melanocyte stimulating hormone (MSH) or vasoactive intestinal polypeptide (VIP), seen in over 98% of patients, has not consistently responded to any treatment modality. Use of replacement VIP has been attempted anecdotally; VIP replacement therapies show promise in short term studies but longer therapies have not been attempted. Here we report an open label trial of 20 patients with refractory CIRS-WDB illness who took replacement VIP in a nasal spray for at least 18 months with confirmation of durable efficacy and absence of significant side effects. These 20 patients were similar in symptoms and lab findings to three previously published cohorts involving 1829 patients and 169 controls. Dosage of VIP was titrated downwards from four to zero doses a day to determine minimum effective dose, and re-titrated upwards for maximum improvement over time. The trial showed that VIP therapy safely 1) reduced refractory symptoms to equal controls; 2) corrected inflammatory parameters C4a, TGF beta-1, VEGF, MMP9; 3) corrected estradiol, testosterone and 25-OH Vitamin D; 4) returned pulmonary artery systolic pressure (PASP) during exercise to normal; and 5) enhanced quality of life in 100% of trial patients. Subsequent identification of correction of T-regulatory cell levels supports the potential role of VIP in both innate and adaptive immune function.
DESCRIPTION

Thymulin is a nonapeptide produced by two distinct epithelial populations in the thymus first described by Bach in 1977. It requires zinc for biological activity. The hormone is involved in T-cell differentiation and enhancement of T and NK cell actions. Thymulin has neuroendocrine effects as well. It follows a circadian rhythm and physiologically elevated ACTH levels correlate positively with thymulin plasma levels and vice versa.

A recent study was done on Zinc Thymulin to test its efficacy in the treatment of hair loss. The study indicated that topical treatment with zinc thymulin significantly increased hair growth over 6 months; further, there were no systemic or local side effects from the treatment. The zinc thymulin metallo-peptide optionally also improves endogenous hair pigmentation. For example, by stimulating melanogenesis in grey or greying hair.

PROTOCOL

Content & Potency: Topical foam provided in a quantity of 50ml foaming applicator.
Suggested dosage: Apply 1ml (2 pumps) to scalp once daily at night.

CLINICAL RESEARCH

doi:10.4172/2167-0951.1000147

Objective: To assess the safety and efficacy of the metallopeptide zinc-thymulin (ZT) for treating androgenetic alopecia (AGA). Previous in vitro studies have described that different thymic peptides can both increase and decrease anagen (thymulin and thymosin beta-4, respectively). Zinc is an essential element and serum zinc deficiency can cause hair loss.

Methods: Eighteen consecutive adult subjects were recruited, 17 males and 1 female, age range 35-90 years (mean 55.4, SD 13.3) with a diagnosis of AGA, Norwood classification 2-7, and hair loss duration range of 3-40 years (mean 15.8, SD 9.6). The trial duration for each subject ranged from 4-10 months. The test compound ZT was synthesized by standard Fmoc peptide protocols and administered in water based topical spray to the scalp. Baseline and after treatment images for hair growth were graded by two blinded assessors using two validated scales: 1. numerical visual analog scale (VAS) for global assessment 2. hair growth index (HGI) of images under higher magnification for percentage changes of vellus, intermediate and terminal hair.

Results: ZT demonstrated no adverse systemic effects or local side effects of redness or scalp irritation in any subject over a total of 3,300 treatment days. Three subjects who were concurrently using minoxidil (N=2) and minoxidil / finasteride (N=1) did not report any drug interaction with ZT. VAS hair assessment improvement was significant in subjects who completed 6 months of treatment (P=0.045, t-test). HGI assessment showed a significant increase in the number of newly observed intermediate hairs in previous “absent hair” regions (P<0.0001) with an average increase of vellus type (32%) and intermediate type (23%) hairs at 6 months. Melanogenesis was observed in several subjects.

Conclusion: Topical applications of ZT demonstrated safety and established efficacy for initiating and maintaining anagen to treat male pattern baldness when applied for>6 months.

A full copy of all trials are available from Tailor Made Compounding Pharmacy. Please contact us for more info.

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