SLEEP+

Rejuvenating, Refreshing,
Restful Sleep*

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TECHNICAL DATA SHEET

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SLEEP+

Fall asleep faster, stay asleep longer, and spend more time in both REM sleep (for brain rejuvenation) and deep sleep (for body restoration). The only patent-pending blend of phytonutrients and essential vitamin/mineral cofactors to support serotonin/melatonin metabolism and improve sleep quality.*

KEY INGREDIENTS

Maizinol™ Corn grass *(Zea mays leaf)* - a proprietary extract derived from the leaves of specifically grown, non-genetically modified Zea mays (corn or maize) using commercial strains of corn approved for human consumption. Maizinol is a patented and natural mood health product that contains 6-methoxybenzoxazolinone (6-MBOA), which can act as a positive regulator of the melatonin system to enhance serotonin levels and improve mood. In addition, Maizinol has been clinically shown address both mental/mood imbalances and to provide sleep-improvement benefits that are superior to melatonin-based sleep aids.*

Griffonia simplicifolia seed extract *(supplying 5-Hydroxytryptophan, 5-HTP)* - the Griffonia simplicifolia plant is found within the Western and Central regions of Africa. Its seeds are rich in the active ingredient, 5-Hydroxytryptophan (5-HTP), a precursor to the neurotransmitter serotonin and the "sleep hormone" melatonin (with the help of cofactors Vitamin B6, C, Zinc and Magnesium). In Native African countries, Griffonia seeds are used medicinally to treat a wide range of stress-induced illnesses. 5-HTP may have a positive effect on sleep, mood, anxiety, appetite, and pain sensation. In addition, 5-HTP has been shown to decrease the time required to fall asleep and reduce the number of nighttime awakenings.*

Pyridoxine HCl / Vitamin B6 - Tryptophan is an essential amino acid that helps regulate nervous system activity related to relaxation and sleep. Vitamin B6 converts a small amount of the tryptophan in your body to niacin, or vitamin B3, and serotonin, a neurotransmitter that helps regulate sleep patterns. By failing to obtain an adequate amount of vitamin B6 in your diet, your body's metabolism of tryptophan may be disturbed. This may limit the amount of serotonin in your body, potentially leading to disturbed sleep patterns and insomnia. Vitamin B6 is also involved in the synthesis of melatonin (through serotonin). Therefore, it may affect sleep by improving the quality of sleep and preserving the circadian rhythm.*

Vitamin B12 / Methylcobalamin - Cobalamin or vitamin B12 is important for a number of essential processes in the body including the production of DNA and RNA, the regulation of blood cell formation and the maintenance of neurons. Much like folate deficiency, vitamin B12 deficiency results in anemia, nerve damage, depression, memory impairment, irritability, psychosis and personality changes. Vitamin B12 deficiency causes depression and other psychological symptoms because the vitamin is required for the formation of neurotransmitters such as serotonin and dopamine. These symptoms are further worsened when folate deficiency is also present. Therefore, vitamin B12 supplementation can improve sleep by providing relief for depression and by preventing damage to nerve cells in the brain.*

Niacinamide / Vitamin B3 - The exact mechanism by which niacin improves sleep is unclear. However, it appears that low niacin levels disrupt the firing of brain neurons and, therefore, affects the sleep-wake cycle. In addition, low niacin levels promote depression and has been linked to anxiety disorders. These can affect the quality of sleep. Therefore, by treating depression and anxiety, niacin can also improve sleep. In a 2005 review published in the Journal of Clinical Sleep Medicine, the authors reported a small study in which niacin was given to a group of participants for 23 days. The result of the study showed that niacin slightly improved REM (rapid-eye movement) sleep. The same group of researchers also gave niacin to women with insomnia and found that the vitamin improved the quality of sleep.*

Folic Acid Powder / B9 – Folic acid or vitamin B9 is another essential B vitamin. Its actions and uses are intertwined with those of vitamin B12. Folate deficiency causes a number of symptoms including irregular heartbeat, anemia, nerve damage, mental confusion, impaired memory, depression, headaches and irritability. These symptoms can affect sleep either directly or indirectly. Depression, mental confusion, irritability and impaired memory are signs of neurotransmitter imbalance and damage to the neurons of the central nervous system. These psychological symptoms can make sleeping difficult and cause insomnia. Therefore, treating folate deficiency may help improve sleep.*

Ascorbic Acid / Vitamin C – Essential for serotonin production. Studies show that a lack of vitamin C may cause shorter and nonrestorative sleep. According to a report in the August 2014 issue of PLoS One, people with low blood levels of vitamin C had more problems with sleep disturbances, such as waking up during the night. Vitamin C is also required to produce dopamine, norepinephrine and epinephrine — neurotransmitters that boost physical and mental energy and feelings of reward and satisfaction.*

Vitamin D3 - Vitamin D regulates the conversion of tryptophan into serotonin.*

Magnesium - Sufficient levels of magnesium are required to stimulate melatonin synthesis and maintain optimal nerve transmission. Not only can magnesium help you get to sleep, but it plays a part in helping you achieve deep and restful sleep as well. Magnesium deficiency has been shown to result in sleep patterns that were light and restless – an effect that is partially due to magnesium's influence in "calming" the nervous system.*

Zinc - plays an essential role in neurotransmitter function and helps maintain cognition, due to it's role in both melatonin and dopamine metabolism.*

CLINICAL STUDIES

J Int Soc Sports Nutr. 2013; 10(Suppl 1): P26.

Effect of Monocot Grass Extract (MGE) on mood state and sleep patterns in moderately stress subjects

SM Talbott and JA Talbott

Abstract

Background

Overtraining syndrome (OTS) is a stress-related phenomenon experienced by elite-level and recreational athletes alike. Athletes are subjected to stressors from physical, psychological, and biochemical sources that may lead to OTS and significant decrements in mental and physical performance. OTS may be characterized by elevated perceived stress, reduced mood quality, increased tension/anxiety, and disrupted sleep quality/quantity; each of which can influence and compound the other, leading to a vicious cycle of increasingly poor performance, increased stress, and disrupted sleep patterns.

Methods

In this study, we supplemented moderately stressed subjects with an extract of monocot grasses (corn grass, wheat grass, and bamboo). Previous animal studies have shown significant anti-stress and relaxation benefits of monocot grass extracts (MGE), likely due to their content of plant metabolite 6-MBOA (6-methoxybenzoxazolinone) and its ability to influence serotonin levels. Fifty-two subjects were randomly assigned in double-blind fashion to receive MGE (N=27, 18 Female & 9 Male) or Placebo (N=25, 17 Female & 8 Male) for 4 weeks. We measured Mood State (Profile of Mood States), Sleep Quality (Pittsburgh Sleep Quality Index), and Sleep Patterns (ZEO Sleep Monitor) before and after 4 weeks of supplementation. Differences between MGE/Placebo at week 4 were analyzed by paired t-tests with an alpha level of 0.05 and reported as percent-difference between groups.

Results

Compared to the Placebo group, the MGE group (all $p < 0.05$):

- Had 8% less Tension (7.9 + 5.9 v. 8.6 + 5.5)
- Had 15% less Depression (6.8 + 6.9 v. 8.0 + 7.9)
- Had 25% less Irritability (6.4 + 5.0 v. 8.0 + 7.9)
- Fell asleep 33% faster (0.63 + 0.79 v. 0.84 + 0.90)
- Had 50% better sleep "efficiency" (0.26 + 0.59 v. 0.52 + 0.71)
- Had 40% better sleep "quality" (0.67 + 0.48 v. 1.12 + 0.97)
- Woke up 30% fewer times each night (2.1 + 2.5 v. 3.0 + 1.5)
- Experienced 24% more time in deep REM sleep (1.85 + 0.46h v. 1.41 + 0.30h)

Conclusion

Overall, these results indicate that the MGE supplement is effective in improving sleep quality and improving stress-related mood states in a population of moderately stressed subjects. Future studies are warranted to evaluate the specific effects of MGE in alleviating OTS in athletes and possibly improving physical and mental performance.

Foods 2015, 4, 130-139.

A Prospective Randomized Double-Blind Study Evaluating UP165 and S-Adenosyl-L-Methionine on Depression, Anxiety and Psychological Well-Being.

DS Kalman, S Feldman, RR Vazquez, and DR Krieger

Abstract

The primary objective of this pilot clinical trial was to evaluate the effects of UP165 (derived from Zea mays L., commonly known as corn) over time. The secondary objective was the comparison for outcomes versus S-adenosyl-methionine (SAM-e). Subjects with mild depression or anxiety were given the Beck Depression Inventory second edition (BDI-II), the Beck Anxiety Inventory (BAI), and the Schwartz Outcome Scale (SOS-10). Forty-two subjects (21–65 years old) were randomized to eight-weeks of supplementation with UP165 or SAM-e with questionnaires being administered at randomization, week four and eight. Those receiving UP165 achieved significant reduction from baseline at weeks four and eight, respectively for the BDI-II, as well as a trend for reduction in BAI at week four and significance at week eight. There was a trend for improvement on the SOS at week four and significance at week eight. SAM-e demonstrated a trend for improvement on the BDI-II by week eight over the UP165 with no differences between the two for the BAI or the SOS. Overall, this study indicates that there may be benefit to UP165 for mood enhancement in those with mild depression or anxiety. Randomized placebo comparator trials appear warranted.

CLINICAL DATA – Unpublished Research & Development Results (Unigen Pharma)

Summary

- Maizinol shows significant mood improvement in adults with a clinical diagnosis of mild to moderate depression.
- Maizinol shows significant improvement in ameliorating depression and anxiety among adults with mild to moderate depression and anxiety.
- Maizinol is equally effective as SAM-e in supporting mood and well-being but at a lower serving size and more convenient once-a-day dosage.
- Safe for human consumption at the recommended daily dosages.
- Non-habit forming and fewer possible side effects than SAM-e.

The following section refers to the three human clinical trials that were performed to evaluate the efficacy and safety of Maizinol.

CLINICAL TRIAL #1

Study Design

The first human trial was performed with an extract of natural corn leaves spiked with a dose of 15 mg/daily dose of synthetic 6-MBOA, based on early anecdotal reports of use of this dose in humans without adverse effects and with reports of positive effects on animal models.

The trial was a double blind, placebo-controlled, cross over trial in 15 healthy males. Screened subjects did not have a clinical diagnosis of depression; however, 2 enrolled subjects exceeded the Hospital Anxiety and Depression Scale (HAD) threshold for evidence of depression (Threshold=20; scores were 21.0 and 23.0).

The trial consisted of 3 phases:

- Phase 1 - subjects were randomly assigned to receive the 6-MBOA spiked extract or placebo for 14 days.
- Phase 2 - consisted of a seven-day washout, during which no study product was taken.
- Phase 3 - subjects were crossed-over to the alternate arm, while maintaining the blind.

Measurement & Analysis

During the 3 phases, the HAD and the Arizona Sexual Experience Index (ASEX, for sexual dysfunction) were administered weekly. In addition, physical exams and laboratory analysis were performed prior to Phase 1, between the Phases, and at the end of Phase 3. General comments about the study products were also elicited after the trial was completed. Fourteen subjects completed the trial.

Results

Including those subjects without initial evidence of depression on the HAD scale, a significant improvement in mood as assessed by this instrument was seen in 12 out of 14 subjects during the 2 weeks they were on the 6-MBOA spiked extract; no statistical change occurred during the 2 weeks in which subjects were on placebo. No changes were seen for subjects on the ASEX scale during either the 6-MBOA or placebo phases; however, subjects did spontaneously report improved sexual functioning during the end-of-study interview.

It is notable that no adverse effect on sexual functioning was detected during the trial, for a product with anti-depressant activity as this is a common side effect of prescription anti-depressant drugs.

CLINICAL TRIAL #2

Study Design & Measurement

The second clinical trial involved open-label, non-controlled administration of 20 mg synthetic 6-MBOA to 8 females with confirmed clinical depression (scored > 20 on the HAD Index) for 6 weeks. Assessments were performed every 2 weeks on the female subjects.

Results

Six out of the eight subjects showed responses to the open-label 6-MBOA, with an average decrease of 10.5 on the HAD Index over the 6 weeks. Although only 8 subjects were involved, the decreases in HAD scores obtained significance ($p<0.031$). No negative effects on sexual function were reported. (Internal communication from Seroctin Technologies, non-published data.)

SAFETY

In each of the aforementioned pilot human clinical studies, 15-20mg of synthetic 6-MBOA administered once a day was well-tolerated. The only side effect reported that could be potentially related to 6-MBOA was reports of mild gastrointestinal upset (transient nausea and indigestion).

CLINICAL TRIAL #3

A third human clinical trial evaluated the safety of the current formulation of Maizinol containing natural 6-MBOA. The 8-week study compared Maizinol to SAM-e (S- adenosylmethionine), a dietary supplement currently marketed for support of mood function.

Study Design

This was a randomized, double-blind, positive-controlled study of the safety of Maizinol and its effects on assessments of depression, anxiety, and well-being. This study enrolled adult male and female subjects, age 21–65 (inclusive), with complaints of mild depression and/or anxiety and with scores between 10 and 19 on the BDI-II and/or between 10 and 21 on the BAI (inclusive). Subjects were not currently taking nor had taken medications for depression and or anxiety in the past year. Subjects were either diagnosed with very mild depression and/or anxiety, or had no prior diagnosis of either disorder. Subjects with moderate or severe depression as defined by a score of > 19 on the BDI-II or subjects with moderate or severe anxiety as defined by a score of > 21 on the BAI were excluded from the trial.

The products tested were as follows:

- Maizinol (which contained not less than 0.2% natural 6-MBOA) 250 mg /day
- SAM-e (S-adenosylmethionine) 400 mg /day
- Placebo - microcrystalline cellulose with 0.5% magnesium stearate

The SAM-e group received a 200mg tablet in the AM dose and a 200mg tablet as the PM dose; the Maizinol group received a 250mg tablet in the AM dose, and placebo matched tablet in the PM dose.

Objectives

The primary efficacy objective of this study was to evaluate the effect of Maizinol on measures of depression, anxiety, well- being and sexual activity and compare to SAM-e in 40 subjects with mild depression and/or anxiety. The secondary efficacy objective of this study was to compare the effects of Maizinol to the dietary supplement SAM-e with regards to depression, anxiety, well-being and sexual functioning as measured by BDI-II, BAI, SOS-10, and ASEX scores in subjects with complaints of mild depression and anxiety.

Results

Both treatment groups showed significant decreases (improvements) in BDI-II scores from baseline to Week 4 and to Week 8. In addition, Maizinol is also shown to be equivalent to SAM-e with respect to ameliorating depression. Maizinol shows significant improvement in ameliorating depression and is equivalent to SAM-e in efficacy.

Based on the results summarized, there were significant (or near significant) decreases (improvements) in the Beck Anxiety Inventory score from baseline to Weeks 4 and Week 8 in both groups. Maizinol was demonstrated to be non-inferior to SAM-e in efficacy, with respect to the amelioration of anxiety. Maizinol was also shown to be equivalent to SAM-e in efficacy (a

stronger result than non-inferiority), with respect to amelioration of anxiety.

SAFETY

No serious adverse events were noted during this trial. Adverse events were generally mild, were judged to be not related, or probably not related to study product, and were of similar prevalence and distribution over organ systems in the two products. No clinically important changes in vital signs (heart rate and blood pressure) or safety laboratory tests were observed. No product safety concerns were raised from this study. No significant changes were observed on the clinical safety chemistry and complete hematology profiles collected at baseline at 4 weeks and 8 weeks.

CONCLUSIONS

Based on the results of this clinical trial, Maizinol and SAM-e both produced significant improvements in the two efficacy endpoints (Depression, Anxiety). Maizinol was shown to be equivalent to SAM-e with respect to amelioration of depression (by the BDI-II scale). In addition, Maizinol was also shown to be equivalent to SAM-e with respect to amelioration of anxiety (by the BAI scale).

Neurochem Int. 2013 Feb;62(3):324-9. doi: 10.1016/j.neuint.2012.12.014. Epub 2013 Jan 7.

Effect of diet on serotonergic neurotransmission in depression.

Shabbir F, Patel A, Mattison C, Bose S, Krishnamohan R, Sweeney E, Sandhu S, Nel W, Rais A, Sandhu R, Ngu N, Sharma S.

Abstract

Depression is characterized by sadness, purposelessness, irritability, and impaired body functions. Depression causes severe symptoms for several weeks, and dysthymia, which may cause chronic, low-grade symptoms. Treatment of depression involves psychotherapy, medications, or phototherapy. Clinical and experimental evidence indicates that an appropriate diet can reduce symptoms of depression. The neurotransmitter, serotonin (5-HT), synthesized in the brain, plays an important role in mood alleviation, satiety, and sleep regulation. Although certain fruits and vegetables are rich in 5-HT, it is not easily accessible to the CNS due to blood brain barrier. However the serotonin precursor, tryptophan, can readily pass through the blood brain barrier. Tryptophan is converted to 5-HT by tryptophan hydroxylase and 5-HTP decarboxylase, respectively, in the presence of pyridoxal phosphate, derived from vitamin B(6). Hence diets poor in tryptophan may induce depression as this essential amino acid is not naturally abundant even in protein-rich foods. Tryptophan-rich diet is important in patients susceptible to depression such as certain females during pre and postmenstrual phase, post-traumatic stress disorder, chronic pain, cancer, epilepsy, Parkinson's disease, Alzheimer's

disease, schizophrenia, and drug addiction. Carbohydrate-rich diet triggers insulin response to enhance the bioavailability of tryptophan in the CNS which is responsible for increased craving of carbohydrate diets. Although serotonin reuptake inhibitors (SSRIs) are prescribed to obese patients with depressive symptoms, these agents are incapable of precisely regulating the CNS serotonin and may cause life-threatening adverse effects in the presence of monoamine oxidase inhibitors. However, CNS serotonin synthesis can be controlled by proper intake of tryptophan-rich diet. This report highlights the clinical significance of tryptophan-rich diet and vitamin B(6) to boost serotonergic neurotransmission in depression observed in various neurodegenerative diseases. However pharmacological interventions to modulate serotonergic neurotransmission in depression, remains clinically significant. Depression may involve several other molecular mechanisms as discussed briefly in this report.

J Huazhong Univ Sci Technolog Med Sci. 2012 Jun;32(3):422-7.

Neurotransmitter-precursor-supplement intervention for detoxified heroin addicts.

Chen D, Liu Y, He W, Wang H, Wang Z.

Abstract

This study examined the effects of combined administration of tyrosine, lecithin, L-glutamine and L-5-hydroxytryptophan (5-HTP) on heroin withdrawal syndromes and mental symptoms in detoxified heroin addicts. In the cluster-randomized placebo-controlled trial, 83 detoxified heroin addicts were recruited from a detoxification treatment center in Wuhan, China. Patients in the intervention group (n=41) were given the combined treatment with tyrosine, lecithin, L-glutamine and 5-HTP and those in the control group (n=42) were administered the placebo. The sleep status and the withdrawal symptoms were observed daily throughout the study, and the mood states were monitored pre- and post-intervention. The results showed that the insomnia and withdrawal scores were significantly improved over time in participants in the intervention group as compared with those in the control group. A greater reduction in tension-anxiety, depression-dejection, anger-hostility, fatigue-inertia and total mood disturbance, and a greater increase in their vigor-activity symptoms were found at day 6 in the intervention group than in the control group (all $P<0.05$). It was concluded that the neurotransmitter-precursor-supplement intervention is effective in alleviating the withdrawal and mood symptoms and it may become a supplementary method for patients' recovery from heroin addiction.

Eur J Pediatr. 2004 Jul;163(7):402-7.

L -5-Hydroxytryptophan treatment of sleep terrors in children.

Bruni O, Ferri R, Miano S, Verrillo E.

Abstract

To test the hypothesis that the administration of L -5-hydroxytryptophan (L -5-HTP) might exert beneficial effects on sleep terrors, we carried out an open pharmacological trial in a group of children with sleep terrors compared to a group of children with the same disorder but without L -5-HTP treatment. Participants in the trial were 45 children (34 males and 11 females; age range

3.2-10.6 years), referred to the Sleep Centre of the Department of Developmental Neurology and Psychiatry of the University of Rome "La Sapienza", affected by sleep terrors. All subjects underwent: (1) complete medical and sleep history; (2) complete neurological examination and EEG recording whilst awake and sleeping, (3) a structured sleep diary for 2 months, (4) after 1 month, all subjects were examined again from the clinical and EEG points of view and (5) after 6 months, a structured interview in order to evaluate the clinical outcome. After the first visit, L -5-HTP was administered (2 mg/kg per day) at bedtime to 31 randomly selected patients for a single period of 20 consecutive days. After 1 month of treatment, 29/31 (93.5%) of patients showed a positive response. In the comparison group without drug therapy, after 1 month, the episodes disappeared only in four children (28.6%) while ten children (71.4%) showed the persistence of episodes with the same frequency as before. After 6 months, 26/31 (83.9%) of children treated with L -5HTP were sleep terror-free, while in five children (16.1%) sleep terror episodes persisted. Of the children in the comparison group, ten (71.4%) continued to show sleep terrors at 6-month follow-up.

CONCLUSION:

To our knowledge, this is the first study demonstrating the efficacy of a new drug treatment for sleep terrors. These results confirm our initial hypothesis and represent evidence that treatment with L -5-hydroxytryptophan is able to modulate the arousal level in children and to induce a long-term improvement of sleep terrors.

Altern Med Rev. 1998 Aug;3(4):271-80.

5-Hydroxytryptophan: a clinically-effective serotonin precursor.

Birdsall TC1.

Abstract

5-Hydroxytryptophan (5-HTP) is the intermediate metabolite of the essential amino acid L-tryptophan (LT) in the biosynthesis of serotonin. Intestinal absorption of 5-HTP does not require the presence of a transport molecule, and is not affected by the presence of other amino acids; therefore it may be taken with meals without reducing its effectiveness. Unlike LT, 5-HTP cannot be shunted into niacin or protein production. Therapeutic use of 5-HTP bypasses the conversion of LT into 5-HTP by the enzyme tryptophan hydroxylase, which is the rate-limiting step in the synthesis of serotonin. 5-HTP is well absorbed from an oral dose, with about 70 percent ending up in the bloodstream. It easily crosses the blood-brain barrier and effectively increases central nervous system (CNS) synthesis of serotonin. In the CNS, serotonin levels have been implicated in the regulation of sleep, depression, anxiety, aggression, appetite, temperature, sexual behaviour, and pain sensation. Therapeutic administration of 5-HTP has been shown to be effective in treating a wide variety of conditions, including depression, fibromyalgia, binge eating associated with obesity, chronic headaches, and insomnia.

Adv Exp Med Biol. 1996;398:373-9.

Fibromyalgia and migraine, two faces of the same mechanism. Serotonin as the common clue for pathogenesis and therapy.

Nicolodi M, Sicuteri F.

Abstract

In this study fibromyalgia sufferers were randomly administered a combination of monoamine-oxidase inhibitors (MAOIs)-A/B with 5-HTP, 5-HTP alone, MAOIs-A/B alone, or the tricyclic drug amitriptyline in order to compare the efficacy of these treatments. The benefits on the painful syndrome were assessed by using Visual Analogic Scale score rating from 0 to 4. The combination of MAOIs with 5-HTP significantly improved fibromyalgia syndrome as determined by Visual Analogic Scale whereas the other treatments yielded poorer benefits. No subject withdrew from the trial due to adverse effects, even if some sleep disturbances and mild stomach-ache were reported. The tolerability of the association MAOIs/5-HTP was good, although a transient cheese effect occurred in one of the patients treated with MAOIs as well as in a patient treated with the association MAOIs and 5-HTP. No one of these two cases was due to pharmacological dietetic mistake of the patient. In both the cases the transient hypertension was associated to very dramatic emotional events. The benefits obtained by using the combination of MAOIs with 5-HTP can be explained with a treatment-induced enhancement of aminergic and serotonergic transmission. The recently shown high prevalence of migraine in the population of fibromyalgia sufferers, suggests a common ground shared by fibromyalgia and migraine. Migraine has been demonstrated to be characterized by a defect in the serotonergic and adrenergic systems. A parallel dramatic failure of serotonergic systems and a defect of adrenergic transmission have been evidenced to affect fibromyalgia sufferers too. Enhancing serotonergic analgesia while increasing adrenergically mediated analgesia seems to be an important tool in fibromyalgia. Treatment consisting with the association MAOIs/5-HTP is aimed at enhancing serotonergic/adrenergic transmission by inducing an up-regulation of serotonergic/adrenergic receptors and a simultaneous increase of serotonin levels in the central nervous system.

J Int Med Res. 1990 May-Jun;18(3):201-9.

Double-blind study of 5-hydroxytryptophan versus placebo in the treatment of primary fibromyalgia syndrome.

Caruso I, Sarzi Puttini P, Cazzola M, Azzolini V.

Abstract

A double-blind, placebo-controlled study of the efficacy and tolerability of 5-hydroxytryptophan (5-HTP) was conducted in 50 patients with primary fibromyalgia syndrome. All the clinical parameters studied were significantly improved by treatment with 5-HTP and only mild and transient side-effects were reported. Further controlled studies are required to define properly the value of 5-HTP in patients with primary fibromyalgia syndrome.