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Recent Advances in Clinical Trials

A Revolutionary Energetic Herbal Honey Formulation for Sex Enhancement for Men and Women

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ABSTRACT

The present patent-pending invention relates to anti-diabetic hypotensive anti-lipid antioxidant sex and immune enhancement herbal formulation mixed with ziziphus mountain sidr honey. Observed results showed excellent results for both men and women suffering from erectile dysfunction with zero side effects. Moreover, the present formulation showed benefit effects on liver, kidney, heart, blood circulation, uric acid, eyesight, irritable bowel syndrome and pulmonary function.

Keywords

Herbal formulation, Anti-diabetic activity, Hypotensive effect, Antioxidant properties, Anti-lipid effects.

Description of the Invention

Hundreds of Millions of men and women suffer from erectile dysfunction, premature ejaculation and poor semen volumes and all chemical sex drugs failed to satisfy the bad needs of men and women besides dangerous side effects. Therefore, people are eagerly waiting for a safe natural formulation to solve their problems.

Common Causes of Erectile Dysfunction

Among causes of poor memory and learning are the following:

- Lack of sleep. Not getting enough sleep is perhaps the greatest unappreciated cause of forgetfulness.
- Medications.
- Poor nutrition
- Anemia
- Poor blood Circulation
- Underactive thyroid(Hypothyroidism)
- Alcohol.
- Smoking.
- Stress and anxiety.
- Depression.
- Erectile dysfunction means not being able to get and keep an erection firm enough for sexual activity. It also is called impotence.

Having erection trouble from time to time isn't always a cause for concern. But if erectile dysfunction is ongoing, it can cause stress, affect self-confidence and add to challenges with a partner. Problems getting or keeping an erection can be a sign of a health condition that needs treatment and a risk factor for heart disease.

Summary of the Invention

The present patent-pending invention relates to anti-diabetic hypotensive anti-lipid antioxidant sex and immune enhancement herbal formulation mixed with ziziphus mountain sidr honey

Details of the Invention

The present patent-pending invention relates to anti-diabetic hypotensive anti-lipid antioxidant sex and immune enhancement herbal formulation mixed with ziziphus mountain sidr honey:
The formulation is composed of the following herbal extracts:

Clerodendron capitatum extract

This is a PDE5 natural inhibitor which was clinically studied by S.I. Abdelwahab et al. [1] results suggest that *C. capitatum* possesses a relaxant effect on CCSM, which is attributable to the inhibition of PDE-5 very close to viagra tablets without any side effects.

Clerodendrum capitatum contains a variety of phytochemicals, including alkaloids, tannins, saponins, triterpenes, anthraquinones, flavonoids, phenolics, and steroids. These compounds contribute to its traditional medicinal uses for treating brain disorders, inflammation, and pain, with studies also suggesting properties related to memory enhancement, pain relief, diabetes, high blood pressure, high lipids and potential antivenom effects.

Bee Pollen extract and Date Palm Pollen extract

A study performed by Mohamed N, et al. [2] showed improvements in male erectile dysfunction as well as diabetes by using bee pollen and or date palm pollen besides increasing sperm volume.

Red Ginseng extract

Korean red ginseng (unskinned *Panax ginseng* before it is steamed or otherwise heated and subsequently dried) is one of the most widely used herbal remedies. This systematic review evaluates the current evidence for the effectiveness of red ginseng for treating erectile dysfunction.

Systematic searches were conducted on 20 electronic databases without language restrictions. Hand-searches included conference proceedings and our files. All randomized clinical studies (RCT) of red ginseng as a treatment of erectile dysfunction were considered for inclusion. Methodological quality was assessed using the Jadad score [3].

Seven RCTs met all the inclusion criteria. Six of the included RCTs compared the therapeutic efficacy of red ginseng with placebo. The meta-analysis of these data showed a significant effect. Subgroup analyses also showed beneficial effects of red ginseng in psychogenic erectile dysfunction.

Horny Goat extract

Epimedium species (aka horny goat weed) have been utilized for the treatment of erectile dysfunction in Traditional Chinese Medicine for many years. Icariin (ICA) is the active moiety of Epimedium species.

Rats were subjected to cavernous nerve injury and subsequently treated for 4 weeks with daily gavage feedings of a placebo solution of normal saline and Dimethyl sulfoxide (DMSO) vs. ICA dissolved in DMSO at doses of 1, 5, and 10 mg/kg. A separate group underwent a single dose of ICA 10 mg/kg 2 hours prior to functional testing. Functional testing with cavernous nerve stimulation and real-time assessment of intracavernous pressure (ICP) was performed at 4 weeks. After functional testing, penile tissue was procured for immunohistochemistry and molecular studies. In separate experiments, pelvic ganglia were excised from healthy rats and cultured in the presence of ICA, sildenafil, or placebo culture media [4].

Rats treated with low-dose ICA demonstrated significantly higher ICP/MAP and AUC/MAP ratios compared with control and single-dose ICA animals. Immunohistochemistry and Western blot were revealing of significantly greater positivity for nNOS and calponin in penile tissues of all rats treated with ICA. ICA led to significantly greater neurite length in cultured specimens of pelvic ganglia.

Radish Seed Extract

A study [5] was conducted to assess the effect of Raphanus sativus extract on the reproductive performance of male wistar rats. a total of 24 male rats were divided into 4 groups (6 of each) namely group A, B,C and D. All groups were given orally 100, 200, 400 and 0.0, mg/kg body weight extract respectively for 30 days. Symptoms caused by acute toxicity were absorbed through the experimental period. At the end of the experiment body weights and sexual organs weights (testes and epididyims) and semen characteristic were determined. Serum was analyzed for testosterone, Follicle-stimulating hormone (FSH), and Luteinizing hormone (LH) levels. The results showed the body weights was significantly decreased, while testicular weight increased. In a dose dependent manner following administration of R. sativus extracts. The extract also improved semen.

Maca Herb Extract

Lepidium meyenii (Maca) is a cultivated root belonging to the brassica family used in the Andean region for its supposed aphrodisiac properties. A double-blind clinical trial on 50 Caucasian men affected by mild erectile dysfunction (ED)was conducted [6], randomised to treatment with Maca dry extract, 2400 mg, or placebo. The treatment effect on ED and subjective well-being was tested administrating before and after 12weeks the International Index of Erectile Function (IIEF-5) and the Satisfaction Profile (SAT-P). After 12 weeks of treatment, both Maca- and placebo-treated patients experienced a significant increase in IIEF-5 score. However, patients taking Maca experienced a more significant increase than those taking placebo). However, only Maca-treated patients experienced a significant improvement in physical and social performance-related SAT-P score compared with the baseline. In conclusion, data support a small but significant effect of Maca supplementation on subjective perception of general and sexual well-being in adult patients with mild ED.

Galangal Extract

Notwithstanding scientific advances, a significant number of the treatments in male infertility remained stayed vague. This study [7] was aimed to study the impact of *AlpiniaOfficinarum* on sex hormones, serum antioxidant and biochemical markers in rats. Forty adult male rats, were partitioned into five groups (each consists of eight rats). The primary group was negative control group (-ve) and fed on basal diet only. The other four groups were subcutaneously injected with a single dose of lead acetate (200 mg/kg b.w) to reduce fertility, then were divided into 4 subgroups: including control positive group, and 2nd, 3rd and 4th subgroup were fed on basal diet with supplementation of dried *A. officinarum* at (5, 7.5 and 10%) respectively for two month. The results revealed that, supplementation with *A. officinarum* caused a significant positive effectson testes which due to a significant increase in the levels of

serum total testosterones, Follicular stimulating Hormone (FSH), Luteinizing Hormone (LH) and Superoxide Dismutase (SOD) levels while Malondialdehyde (MDA) level was diminished. In addition, liver functions and serum lipid profiles were significantly improved compared to the positive control group. In conclusion: Our findings provide a scientific evidence to substantiate *A. officinarum* in improving fertility in human which may be due to its potent antioxidant properties and androgenic activities.

Examples of Pre-Clinical Results

The following results were obtained:

Multinational Clinical Observation

100 men (ages 35 to 88 years) and 20 women in USA, Jordan, Dubai, Saudi Arabia and Oman used the honey mix formulation for 2 weeks with excellent results

Clinical Observation of Royal Honey mix for Energy

It was observed that small spoon of this honey did give excellent energy all day long much better than all energy drinks

Safety and Toxicity Study

No side effects were reported during the use of this Royal Honey mix (toxicity study is attached).

Conclusion

This patented pending formulation was proven to be effective in enhancing sex for both men and women.

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JORDAN UNIVERSITY OF SCIENCE & TECHNOLOGY
Report

Analysis of Toxicological effect of Herbal Mix ROYAL HONEY

Methods:

- Two groups of mice ,each of 10 were used
- Proper amount of the tested extract was used . The extract base without the active ingrediant was used to the control group
- After 0, 6, 12, 18, days blood was collected by heart puncture or tail tip from all mice using EDTA tubes
- the following tests were performed :

A. Physical activity of general appearance
B. Pathological tests : after dissection of animals at the end of the exp. The following organs were examined: liver, pancreas, adrenal gland, heart, liver, and spleen
C. Hematological tests including RBCs &WBCs count.
D. Biochemical tests including :glucose, triglyceride (TG), cholesterol, uric acid, creatinine, ALT, AST, amylase, Total bilirubin

Results

Glucose (mg/dL)

Days	0	6	12	18
Control	116±8	119±9	120±10	118±12
Royal Honey	110±11	115±12	117±8	115±8

Cholesterol (mg/dL)

Days	0	6	12	18
Control	73±10	75±8	78±9	80±10
Royal Honey	70±10	73±9	77±9	76±10

TG (mg/dL)

Days	0	6	12	18
Cotrol	172±25	168±30	180±35	190±35
Royal Honey	180±30	178±25	186±28	191±33

Total bilirubin

Days	0	6	12	18
Control	0.32±0.1	0.33±0.1	0.33±0.1	0.35±0.1
Royal Honey	0.3±0.1	0.3±0.1	0.34±0.1	0.36±0.1

Creatinine (mg/dL)

Days	0	6	12	18
Control	1±0.1	0.9±0.2	1.1±0.2	0.9±0.2
Royal Honey	0.9±0.2	1±0.3	1.1±0.4	1.3±0.4

Uric acid (mg/dL)

Days	0	6	12	18
Control	9.3±1.1	8.8±1.4	8.9±1.5	9.1±1.3
Royal Honey	9.5±1.5	8.7±1.2	8.5±1.5	8.3±1.1

Amylase (U/L)

Days	0	6	12	18
Control	813±80	804±100	790±90	780±85
Royal Honey	930±120	960±130	870±95	910±95

ALT (U/L)

Dayes	0	6	12	18
Control	95±15	90±18	85±20	92±15
Royal Honey	95±15	92±18	90±20	85±20

AST (U/L)

Dayes	0	6	12	18
Control	108±12	102±10	92±13	95±10
Royal Honey	110±12	85±15	75±15	45±10

Weight (gm)

Days	0	6	12	18
Control	20.4	22.1	24.3	26.6
Royal Honey	20.2	23.2	25.1	26.8

Hematology

(RBCs * 10^6 /mm^3)

Dayes	0	6	12	18
Control	5.7±0.6	6.2±0.5	5.8±0.7	5.6±0.5
Royal Honey	5.5±0.5	5.6±0.7	5.7±0.6	5.9±0.6

(WBCs *10^3/mm^3)

Dayes	0	6	12	18
Control	5.2±0.3	4.6±0.4	6.1±0.6	5.8±0.6
Royal Honey	5.1±0.4	5.3±0.5	5.6±0.4	5.5±0.5

Physical activity: The group of mice which received the herbal extract did not exhibit any remarkable difference in general appearance ,but they were very active throughout the study and showed high physical activity compared to the control group.

Summary of results

#	*Parameter tested*	*Comment*
1	Physical activity and general apperance	No effect
2	Weight gain and water consumption	
3	Pathological examination after dissection	No macroscopic changes could be observed
4	Hematology	
4.1	RBCs	No significant changes observed
4.2	WBCs	No significant changes observed
5	Biochemical tests	
5.1	Glucose	No significant changes observed
5.2	Cholesterol	No significant changes observed
5.3	TG	No significant changes observed
5.4	Creatinine	No significant changes observed
5.5	Uric acid	No significant changes observed
5.6	Total bilirubin	No significant changes observed
5.7	ALT	No significant changes observed
5.8	AST	Significant decrease was observed
5.9	Amylase	No significant changes observed

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