The effects of a novel food supplement containing a mixture of herbal extracts and 1.3-1.6-beta-glucan on body composition and weight in females. The results from a randomized placebo-controlled double-blind study in female subjects.

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Abstract

The efficacy and tolerability of a new formulation based on natural ingredients, was investigated in this randomized, placebo controlled, double- blind study. The formulation consists of a mixture of 6 different herbs and 1.3-1.6 β-glucan. The study was carried out in 58 middle aged female subjects with mild to moderate overweight (BMI ≥27.5 kg/m2) and with an average waist circumference (WC≥ 95cm). 30 subjects were treated with the active preparation and 28 subjects with placebo. Two subjects dropped out of the study. The results show that during a treatment period of 30 days significant reductions are seen in waist (WC) and abdominal circumferences (AC) and in the hip circumference (HC) (p≤0.01). No significant differences were seen in Body Weight (BW), Body Mass Index (BMI) or Body Fat (BF %) With respect to the mechanism of action of the treatment it might be that the combination of the herb mixture and the 1.3-1.6-β-glucan might have an anti-inflammatory effect that will reduced the fat accumulation locally as well as effects on glucose and lipid metabolisms that will influence the fat storage. Additional research is warranted to further clarify the mechanisms responsible for these effects.

Key Words: Herbs, β - glucan, overweight, inflammation, controlled study, placebo

Subjects and Methods

Subjects and study design

Sixty none-smoking female subjects with slight to moderate overweight (BMI ≥27.5 kg/m2) were invited to participate in the study. All participants gave written informed consent before entering the study, after having received information about the study procedures. The study was conducted according to the principles of the revised Declaration of Helsinki, Good Clinical Practice and local regulation.

Participants should not use any drugs for chronic diseases or be on any weight reduction treatment during the study period. No diets advice or advices with respect to exercise were given to the participants prior to inclusion in the study. In this short –time study we were interested to confirm or invalidate the observations made in previous open pilot studies studies.

The study was carried out as randomized placebo controlled double- blind study. The treatment period was 30 days.

Treatment

The investigational preparation used in this study was 30 Days® from Med-Eq. AS, Tønsberg, Norway. The product is defined as a food supplement and each tablet contains the following ingredients: 125 mg 1.3-1.6 β-glucan extract from brewer's yeast and 50 mg water extracts (1:10) of each the following herbs, blessed milk thistle seeds (Silybum marianum), golden root (Rhodiola rosea), global artichoke leaves (Cynara scolymus), schisandra fruit (Schisandra chinensis), licorice root (Glycyrrhiza glabra) and dandelion root (Taraxacum). The extraction technology used in extracting the herbs is a patented low temperature technology. As it was the intention to market the product as a food supplement only extracts with water can be used according the regulatory definitions from the Norwegian Medicinal authorities.

The dosage was two tablets in the morning and two tablets in the evening. The tablets were taken together with food and swallowed with water. The choice of daily dose was based on the clinical experience made pre-trial. No formal dose-response studies have been carried out. The total daily dose was thus 500 mg 1.3-1.6 β-glucan and 1200 mg of the herbal mixture. The placebo tablets used in the study contained lactose. The active tablets and the placebos had similar appearances and were packed in similar containers in order to keep the study blinded. In order to avoid any differences in smell between the tablets they were film- coated. The supplement was not on the market when the study to place. All tablets used in this study were supplied by Med –Eq AS, Tønsberg, Norway.

Performance of the study

Subjects interested to participate in the study after having received verbal and written information were randomized to receive either active or placebo tablets in a simple randomization procedure.

Half of the subjects received active tablets and the other half received placebo.

Initially and after 30 days (end of the study) the body weight of the subject was registered on a balance beam medical scale to the nearest 0.1 kg. Stature was measured initially on a portable stadiometer to an accuracy of 0.5cm with the subject barefoot, feet together and head level. Other parameters measured at each visit included waist, abdominal and hip circumferences. These measurements were carried in standardized way and measured on exactly the position at each of the visits and by the same person. Waist circumference was measured on a horizontal plane at the level of the iliac crest using a nonstrech anthropometic tape at the end of a normal expiration

Body composition was measured initially and at the end of the study Body composition was determined with bio-impedance measurement equipment.

The participants were asked to report all side–effects they felt during the treatment period.

Statistical evaluation

Prior to study start, and based on indications with respect to effect of the treatment from the open pilot studies, a simple sample size calculation was performed. This calculation was based on that the probability of mistakenly claiming that the preparation should have an effect in excess of placebo should be maximum 5%. Further if the preparation had an effect in excess of placebo this should be revealed with probability of 95%. These calculations revealed that 60 subjects with 30 subjects in each of the two groups would be sufficient.

Data are given in the text and tables as means ± standard deviations (SDs). Data were analyzed with SAS statistical package version 8.2 and SPSS software 13.0 for Windows. In all analyses a two –sided p value of 0.05 was considered statistically significant.

Results

A total of 58 subjects concluded the study according to the protocol, thirty in the group receiving the active preparation and 28 subjects in the placebo group. Two subjects dropped out of the study, one in the active group because of surgery and one in the placebo groups because she started on another weight reduction regimen.

The demographic and baseline characteristics of the subjects are shown in table 1. As can be seen there are differences in some of the parameters between the two groups The placebo treated subjects have an significant higher initial body weight than the subjects in the active group (80.9 kg vs. 76.2) and a significant higher abdominal circumference (99.0 cm vs. 94.9 cm). For the other parameters it is no significant differences. These initial differences are not, however, making it difficult to draw firm conclusions on the effect of the preparation.

The results from this study are presented in tables 2 and 3. As can be seen from table 2 the body weight (BW), body mass index (BMI) and the body fat BF% were not reduced significantly in the groups receiving placebo or the active preparations, respectively during the study period of 30 days..

From table 3 it can be seen that the reductions in waist (WC), abdominal (AC), hip (HC) circumferences after treatment with placebo is clinically none significant while the same three parameters are reduced significantly in the group receiving the active preparation (p≤0.01).

When the results in the two groups are compared it can be concluded that the reductions in the three circumferences (WC,AC,HC) are significantly in favor of the group receiving the active treatment as compared to the placebo group (p≤0.01)

The subjects that concluded the study according to the protocol did not report any tolerability problems related to intake of the preparations. The two subjects that dropped out of the study did so for reasons not related to the tablet intake.

Discussion

The results from our study is interesting as we are able to reduce significantly the waist, abdominal and hip circumferences even if the total body weight, BMI and BF% not are reduced..As the preparation is containing 1.3-1.6 β-glucan we expect that we have anti-inflammatory as well as lipid lowering effects. The mechanism of action of the herbal part of the preparation is more uncertain. However, it has been published a couple of papers lately that highlights different herb material and their anti-diabetic properties and anti-inflammatory properties [24, 25].

We believe that effects we observe in the circumferences is due to the anti-inflammatory effect that will reduced the fat accumulation locally as well as effects of the preparation on glucose and lipid metabolisms that will influence the fat storage.

The clinical results obtained in this study make the herb and glucan combination an interesting one with an interesting clinical potential. Additional research is warranted to further clarify the mechanisms responsible for the observed effects.

Table 1:

Demographic and baseline characteristics of subjects by treatment group

Characteristic	Control	Active	p
N	28	30	
Gender			
Female n%	100	100	
Race	Caucasian	Caucasian	
Age	42.5(2.5)	43.1(2.7)	ns
BF, %	38.1	37.6	ns
BMI, kg/m2	29.3	28.3	ns
Weight, kg	80.9	76.2	0.05
Height, cm	166.0	164.0	ns
WC,cm	97.4	95.8	ns
AC,cm	99.0	94.9	0.05
HC,cm	98.5	96.6	ns

Table 2:

Development of BW, BMI ,and BF% on placebo and active treatment SD in parentheses. ns mean no significance. N=58

Group	Parameter	Baseline	After 30 days	Diff	p-value
Placebo	BW(Kg)	80.9(6.2)	80.3(5.7)	0.6	ns
N=28	BMI(Kg/m2)	29.3(3.1)	29.1(2.9)	0.2	ns
	BF(%)	38.1(3.7)	37.6(3.5)	0.5	ns
Active	BW(Kg)	76.2(6.0)	75.7(5.9)	0.5	ns
N=30	BMI(Kg/m2)	28.3(2.6)	28.1(2.5)	0.2	ns
	BF(%)	37.6(3.2)	36.9(3.0)	0.7	ns

Table 3:

Development of WC, AC, and HC on placebo and active treatment. SD in parentheses. ns. means no significance. N=58

Group	Parameter	Baseline	After 30 days	Diff	p-value
Placebo	WC(cm)	97.4(6.5)	96.4(6.7)	1.0	ns
N=28	C(cm)	99..0(8.0)	98.2(8.3)	0.8	ns
	HC(cm)	98.5(7.5)	98.4(7.7)	0.1	ns
Active	WC(cm)	95.8(7.6)	94.0(7.4)	1.8	p≤0.01
N=30	AC(cm)	94.9(8.2)	93.1(7.7)	1.8	p≤0.01
	HC(cm)	96.6(8.0)	95.0(7.8)	1.6.	p≤0.01