



**Draft II Publication**

**The effect of a novel food supplement containing a mixture of water extracted herbs and 1.3-1.6-beta-glucan on body composition and weight in females. The results from a blinded placebo-controlled pilot study.**

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# The effect of a novel food supplement containing a mixture of water extracted herbs and 1.3-1.6-beta-glucan on body composition and weight in females. The results from a blinded placebo-controlled pilot study.

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## Summary

The results from this placebo controlled clinical study in 28 middle age females with mild to moderate overweight (BMI  $\geq 27.5$  kg/m<sup>2</sup>) and with a waist circumference (WC  $\geq 90$  cm) show during a treatment period of 30 days significant reductions in body weight, BMI, BF% as well as significant reductions of waist, abdominal and hip circumferences. 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- $\beta$ -glucan has a favorable effect on the gastrointestinal system digestively as well immunologically.

Key Words: Herbs, glucan, overweight, fat reduction.

## Introduction

The metabolic syndrome, operationally defined as presence of any three of the following factors: Central obesity (high waist circumference), hyperglycemia, high blood pressure, low high-density lipoprotein cholesterol (HDL-C) or high triglycerides has recently been recognized as a public health concern. While the metabolic syndrome alone is a condition of disabling medical sequel, it is an intermediary step in the progression of a number of vascular and coronary-related clinical events. Observational evidence suggests that central obesity is a key element of the metabolic syndrome, and recent studies suggest an etiologic role for visceral adipose tissue.

For several years it has been known that a waist line circumference of  $\geq 80$  cm in females and  $\geq 94$  cm in males have been proposed to be used as a clinical cardiovascular risk assessment and interpretation of health risks,

Even if big resources have been used on research and treatment of obesity during the last decades the results have been disappointing according to reports from WHO. We have not been able to reduce the epidemic dimension of overweight and obesity in the way we have approached the problem. Different alternative ways should be tried in order to solve the problems.

Obesity is generally considered as the end result of a long standing positive energy

balance. Although no one disputes the laws of thermodynamics, some alternative suggestion for the etiology of obesity have been discussed. The expression "infectobesity" describes the possibility that obesity may be associated with viral infections or a particular behavior of the intestinal bacterial mass. Although the causes for obesity are unclear it seems that environmental, genetic, neural and endocrine factors contribute to its development. The rapid global spread of obesity resembles epidemiologically the spread of an infectious disease. Surprisingly, little consideration has been given to the possibility that the epidemic of obesity could be due to an infectious agent.

However, in animals, seven viruses and a scrape agent have shown to cause obesity, and adenoviruses Ad-31 and Ad-9 have been shown to be radiogenic in animal cell cultures. In humans, small EDRK-rich factor 1A (SMAM-1), an avian adenovirus 36 (Ad-36). Studies have conformed that humans as well as animals with obesity can have infections. In order to treat such infections the search for suitable agents has started.

From the literature there is also evidence to indicate that the body's natural weight –control mechanisms are not functioning properly in obesity. Because the obesity epidemic occurred relatively quickly it has been suggested that **environmental** causes instead of genetic factors may be largely responsible. What has, up to now, been overlooked is that earth's environment and usage of has changed significantly during the last decades because of the exponential production and usage of synthetic organic and inorganic chemicals. Many of these chemicals are better know for causing weight loss at high levels of exposure but much lower concentrations of these chemicals have powerful weight –promoting actions. This property has already been widely exploited commercially to produce growth hormone that fatten livestock and pharmaceuticals that induce weight gain in grossly underweight patients. One hypothesis is therefore that the current level of human exposure to these chemicals may have damaged many of the boy's natural weight-control mechanisms. It might be that these exposures may have damage many of the

body's natural weight-control mechanisms. It might be that these effects , together with a wide range of additional, possibly synergistic factors may play a significant role in the worldwide obesity epidemic.

Certain criteria have to be met for such agents that shall be used for long-term treatment. Based on favorable clinical pilot experiences with a combination of a mixture of herbs and 1, 3-1, 6 beta glucan in reducing fat deposits we decided to carry out a placebo controlled blinded study

Here we present the results of a clinical trial in Norwegian females using a preparation containing 1, 3-1, 6 beta glucan and a combination of different herbs. The composition is described below (Material and Methods). The primary outcome was decreased weight, BMI, waist, stomach and hip circumferences as well as tolerability.

## Subjects and Methods

### Subjects

Female subjects with slight to moderate overweight (BMI  $\geq 27.5$  kg/m<sup>2</sup>) 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. No diets advice or advices with respect to exercise were given to the participants before inclusion in the study. In this short –time study we were interested to study the effect of the preparation when other factors were kept unchanged.

### Study design

The study was carried out as placebo controlled single blind study in the following way. Twelve of the participants started the study with a 30 day placebo period. They were controlled initially and then after 30 days. At conclusion of the placebo period they were switched to the active preparation for a period of 30 days. Another group of 16 participants started at the same directly on treatment with the active treatment. In this way 28 participants were receiving the active treatment for a period of 30 days. All the subjects were then controlled after 30 days on active treatment.

## Treatment

The investigational preparation used in this study was 30 Days® from Med-Eq AS. 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 (*Silybum marianum*), golden root (*Rhodiola rosea*), globe artichoke (*Cynara scolymus*), schisandra (*Schisandra chinensis*), licorice root (*Glycyrrhiza glabra*) and dandelion (*Taraxacum*).

The mixture of these herbs, which all have a specific effect on gastrointestinal function through a detoxification effect.

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 herb mixture. The placebo tablets used in the study

contained lactose. All tablets used in this study were supplied by Med –Eq AS, Tønsberg, Norway.

## Performance of the study

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.

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

## Statistical evaluation

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

The results from this study are presented in the following tables 1 and 2. As can be seen from table 1 both the body weight (BW), body mass index BMI and the body fat BF% were reduced significantly during the study period of 30 days when the subjects were taking the active preparation (30 Days®). For the 12 patients starting with a 30 days treatment with placebo no statistical differences were seen in any of the parameters.

The average weight reduction in this study is 1.8 kg giving a weekly weight reduction of approximately 0.5 kg. The average waist reduction is 3.8 cm, while the abdominal circumference

Most of the subjects participating in this study reported that their gastrointestinal functions were normalized after starting taking the active preparation. Quite a few of the participants had suffered from constipation before entering the study. After starting the study the constipation disappeared and they had an improved gastrointestinal function during the study and felt much better in that respect.

The tolerability of the treatment was excellent and none of the participants had any problems with side-effects of the active treatment during the study period.

## Discussion

The results from this study indicate that the preparation used has a very favorable effect on reducing fat deposits documented through the quite impressive reduction of waist circumference of 3.8 cm and similar reductions in abdominal and hip circumferences.

The reduction of body weight is also quite satisfactory, and it is impressive that almost 100% of the weight loss is due to fat loss

The combination of 1.3 -1.6  $\beta$ -glucan and the mixture of herbs might be a good treatment for metabolic syndrome which today is renamed systemic inflammatory response syndrome (SIRS). Obesity creates a low-grade SIRS that is similar (but on a smaller scale) to gram-negative sepsis. This process involves up-regulation of systemic immunity, is characterized clinically by insulin resistance and metabolic syndrome, and put the subject at increased risk for organ failure, infectious morbidity and mortality. Through lipotoxicity and cytokine dysregulation, obesity may act to prime the immune system, and predisposing to an exaggerated subsequent immune response when a second clinical insult occurs (such as trauma, burns, or myocardial infarction), Specialized nutrition therapy for such patients currently consist of hypocaloric,high protein diet. However, this approach does not address the putative pathophysiological mechanisms of inflammation and altered metabolism associated with obesity. A number of dietary agents such as arginine, fish oil, and carnitine may correct these problems at the molecular levels. Pharmaconutrition formulas may provide exciting innovation for the nutrition therapy of the obese patient.

$\beta$ -glucan has been studied for over twenty years for their favorable biological effects in mammals. It is common knowledge in the scientific community that  $\beta$ -glucan is the most known powerful immune stimulant and a very powerful antagonist to both benign and malignant tumors; it lowers cholesterol and triglyceride levels, normalizes blood sugar level, heals and rejuvenates the skin and has various other benefits.

In recent study it was shown that consumption of a diet high in  $\beta$ -glucan reduced the visceral fat area, waist circumference as well as the serum low-density lipoprotein cholesterol (LDL-C) and total cholesterol (TC) in hypercholesterolemic Japanese men.

By recognizing the role of toxins in obesity and altered function of the neuroendocrine-immune and the mitochondrial and redox systems, and by creating a comprehensive strategy for both reduction of exposure to and elimination of toxins, as well as the development of effective clinical strategies, treatment resistance to obesity may be more successfully addressed. Further research is needed to explore the clinical relevance and the mechanisms that underlie this hypothesis and to examine clinical detoxification methods.

The favorable results obtained with the food supplement used in this pilot study on fat deposits should be followed up on a larger group of participants where also serum concentration of lipids should be followed. It would also be interesting to study the long-term effect of the treatment with this food supplement product.

In conclusion, intake of the food supplement used in this study significantly and safely reduced body weight, body fat and body mass index as well as waist, abdominal, and hip circumferences. The preparation seems to have beneficial effects in preventing the metabolic syndrome.

**Table 1: Development of BW,BMI and BF% on placebo and active treatment SD in parentheses. Ns mean no significance.**

<b>Group</b>	<b>Parameter</b>	<b>Baseline</b>	<b>After 30 days</b>	<b>Diff</b>	<b>p-value</b>
<b>Placebo</b>	BW(Kg)	78.1	78.0	0.1	ns
<b>N=12</b>	BMI(Kg/m <sup>2</sup> )	28.0	28.0	0.0	ns
	BF(%)	39.8	39.8	0.0	ns
<b>Active</b>	BW(Kg)	77.1	75.3	1.8	
<b>N=28</b>	BMI(Kg/m <sup>2</sup> )	28.1	27.5	0.6	
	BF(%)	39.4	37.9	1.5	

**Table 2: Development of WC,AC and HC on placebo and active treatment. SD in parentheses. Ns means no significance.**

<b>Group</b>	<b>Parameter</b>	<b>Baseline</b>	<b>After 30 days</b>	<b>Diff</b>	<b>p-value</b>
<b>Placebo</b>	WC(cm)	91.0	91.0	0.0	ns
<b>N=12</b>	AC(cm)	96.7	96.8	0.1	ns
	HC(cm)	100.3	100.2	0.1	ns
<b>Active</b>	WC(cm)	94.9(7.6)	91.1(7.4)	3.8	p≤0.01
<b>N=28</b>	AC(cm)	96.5(8.2)	92.4(7.7)	4.1	p≤0.01
	HC(cm)	99.7(8.0)	95.7(7.8)	4.0	p≤0.01

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