

A Randomized, Double-blind, Placebo-controlled Trial of a New Weight-reducing Agent of Natural Origin

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The efficacy and tolerability of a new weight-reduction agent, based on natural ingredients, was investigated in this randomized, placebo-controlled, double-blind study. The product reduces the absorption of different types of sugar from the gastrointestinal tract. Forty obese volunteers were included in the 12-week study. Body weight, body composition and blood pressure were recorded at baseline and every month during the study. The results show a significant difference in weight reduction in favour of the active group (3.5 kg versus 1.2 kg). Body composition measurements showed that > 85% of the reduction in the active group is fat loss. The tolerability was similar and good in both groups. This product shows promising results and should be studied more extensively at different dose levels.

KEY WORDS: WEIGHT REDUCTION AGENT; NATURAL INGREDIENTS; WEIGHT LOSS; OBESITY

***I*NTRODUCTION**

Obesity and being overweight are now major health problems in several countries. Many life-style diseases, such as high blood pressure, type-II diabetes and hyperlipidaemia are linked to being overweight. The World Health Organization (WHO) recently published a report on the epidemic development of overweight and obesity, and has proposed

measures to reduce and/or stop this development.¹ The only effective measures in the long run are changes in food intake and physical exercise, but a number of agents, drugs or natural substances, are available to help in initiating weight reduction. These agents can be used in combination with sustained changes of food intake and exercise habits.

A balanced diet involves the balanced intake of carbohydrates, fat and proteins. Carbohydrates generally represent about 55% of calorie intake, compared with 30% as fat and only 12% as proteins. Nutritional experts recommend that fat intake is restricted to less than 30% of the daily energy intake, in order to improve cardiovascular health and avoid weight problems. Carbohydrate intake should also be monitored: where the level of carbohydrates exceeds the body's requirements, insulin converts the carbohydrates into fat, which leads to weight gain. Lack of physical exercise or activity adds to the problems associated with a high-calorie diet. Methods currently used for dietary control include a well-balanced diet with reduced calorie intake and/or physical activity or exercise. Low-carbohydrate diets are restrictive in terms of food choices, are hard to manage and are inevitably difficult to adhere to. Exercise, unless carried out regularly, has little effect on weight control.²⁻⁴ Thus, there is a need for alternative means of weight control.

After a high-carbohydrate meal, glucose levels rise rapidly, stimulating the release of insulin which promotes the utilization of glucose, but also signals the body to store fat and prevent the mobilization of previously stored fat. Glucagon secretion is suppressed by the high glucose level. A high-protein meal, however, causes an imperceptible rise in blood glucose and, consequently, a very small rise in insulin, but a significant increase in the level of glucagon, which promotes the mobilization of previously stored fat.⁵

A new dietary formulation comprising natural ingredients, which work together to capture excess sugars and reduce or prevent their storage in the body as fat, has recently been developed. This formulation overcomes the problem of low-carbohydrate diets since it changes carbohydrate absorption without the need for a change in diet.⁶

The product contains an α -amylase inhibitor extracted from kidney beans (*Phaseolus vulgaris*) with the trade name Phaseolamin[®] (Leuven Bioproducts, Belgium), a glycoprotein with a molecular weight in the range 42 000 – 49 000 and approximately 8% of its molecular weight consisting of carbohydrates. This component is intended to block the action of pancreatic α -amylase in the intestine, inhibiting the conversion of the large starch molecules into small sugar molecules, which can be directly absorbed. Consequently, most of the starch is eliminated from the body by excretion.⁷

Another component of the product is inulin, which is obtained, industrially, from chicory roots (*Chicorium*), and is available under the trade name Raftiline[®] (Orafti SA, Belgium). Inulin reduces the absorption of sugar molecules in the small intestine, and is believed to suppress appetite and saturate the sweet taste receptors on the tongue.⁸

The third active ingredient in the product is *Garcinia cambogia*, which contains hydroxycitrate and is capable of reducing or preventing the uptake of fat from the small intestine.⁹⁻¹¹

We have carried out a controlled clinical study of the activity and tolerability of the product in overweight and obese people, which have not, to our knowledge, been studied previously.

SUBJECTS AND METHODS

SUBJECTS

Forty volunteers of both sexes, aged 18 years or more, were recruited through an advertisement in a local newspaper. All of the volunteers had a body mass index (BMI) in the range 27.5 – 39.0 kg/m² but were otherwise healthy. All participants gave written informed consent. A regional ethics committee approved the study, which was conducted according to the

principles of the Declaration of Helsinki, good clinical practice and local regulations.

STUDY DESIGN

The study was designed as a randomized, double-blind, placebo-controlled trial with two arms. Subjects were randomized either to active treatment or placebo using a simple block randomization procedure with sex as a stratification criterion. Two tablets of the product (Suco - Bloc®) were taken immediately after breakfast, lunch and dinner for 12 weeks. The tablets weighed 650 mg and each contained approximately 200 mg *Phaseolus vulgaris* extract, 200 mg inulin and 50 mg *Garcinia cambogia* extract. Placebo tablets had the same weight and appearance as the active tablets but contained no active ingredients. Both active and placebo tablets were supplied by Med-Eq Ltd, Tønsberg, Norway.

Before the start of the study the participants were given diet lists with advice on low-fat foods, supplying an energy intake of approximately 1200 kcal (5 KJ) per day, and were recommended to use this diet during the study.

DEMOGRAPHIC DATA

Volunteer characteristics: sex, weight, height and age were obtained at baseline (week 0; Table 1). Body weight (with the subject in

standardized lightweight clothes on each occasion) was registered on a balance beam medical scale to the nearest 0.1 kg and stature was measured initially on a portable stadiometer to an accuracy ± 0.5 cm with the subject barefoot, feet together and head facing forward. Body composition was measured at baseline, and at weeks 4, 8 and 12 by the near infrared technique using a Futrex 5000 A instrument (FUTREX Inc; Gaithersburg, USA)^{12,13} as well as with Bio Impedance Assessment (Gaia Body analyser, BME, Bordeaux, France). Standardized hip and waist circumferences were measured at baseline, and at weeks 4, 8 and 12. Blood pressure was measured in the sitting position at baseline, and at weeks 4, 8 and 12 following a standardized procedure and using a digital blood pressure manometer.

STATISTICAL ANALYSIS

A two-tailed Wilcoxon signed rank test was used to measure mean changes from before to after treatment. For each significance testing a 5% level was used. SAS (version 6.0) software was used for all statistical analyses.

RESULTS

No significant differences were found between the groups at baseline in

TABLE 1

Baseline characteristics of obese volunteers given weight-reduction agent or placebo

Group	Sex	Age (years)	Weight (kg)	Height (cm)	BMI	BF (%)
Active	18 female/2 male	45.6 \pm 13.2	86.4 \pm 6.0	166.9 \pm 9	31.0 \pm 3.2	30.2 \pm 2.7
Placebo	18 female/2 male	39.7 \pm 12.9	89.7 \pm 8.2	168.1 \pm 8	31.7 \pm 2.9	29.7 \pm 2.5
<i>P</i> -values ^a	0.73	0.80	0.82	0.84	0.85	0.87

^a*P*-values for differences between the two treatment groups (ANOVA F-test).

BMI, body mass index; BF, body fat.

Values are means \pm SD.

Natural substance for weight reduction

demographic variables: sex, weight, height, age and percentage body fat (Table 1).

Six participants in the placebo group dropped out of the study, while one dropped out in the active group. These subjects did not attend for measurements; when we contacted them they said that they lacked the motivation to continue, but they are all included in the analysis.

Table 2 shows the changes in weight and BMI during the study. The weight loss and BMI reduction in the active group were statistically significant. No statistically significant changes in weight or BMI were seen in the placebo group. The body mass analyses show that the weight loss in the active group consisted mainly of fat loss as > 85% of the weight loss was accounted for by fat. Body fat composition measurements with the two different methods used showed a high and significant degree of correlation.

No significant changes in blood pressure, or in hip or waist circumferences, were seen during the study (results not shown).

None of the participants in either group reported any side-effects.

DISCUSSION

The results of this study show that the active preparation has a significantly greater effect on body weight than does the placebo (weight loss of 3.5 kg versus 1.2 kg).

All participants were given diet lists with low fat meals giving an estimated daily energy intake of approximately 1200 kcal. Several participants informed us that they had not used the diet lists but had eaten as before. If the majority of the subjects had followed the 1200 kcal/day diet one would have expected a more pronounced weight reduction during the observation period. Bearing this in mind, however, the weight reduction results are promising.

As this is the first controlled study with the product, little information was available on the appropriate daily dose of the product. The present dose was based on open studies

TABLE 2

Changes in weight, body mass index (BMI) and body fat (BF, %) during treatment of obese volunteers with weight-reduction agent or placebo

		Week				Change, week	
		0	4	8	12	0 – 12	P-value ^a
Weight (kg)	Active	86.4 ± 6.0	85.0 ± 6.2	83.5 ± 6.0	82.9 ± 6.3	3.5 ± 2.0	0.001
	Placebo	89.7 ± 8.2	89.0 ± 9.0	88.4 ± 8.5	88.4 ± 8.6	1.3 ± 1.4	NS
BMI (kg/m ²)	Active	31.0 ± 3.2	30.5 ± 3.0	29.9 ± 3.1	29.7 ± 3.2	1.3 ± 1.2	0.01
	Placebo	31.7 ± 2.9	31.4 ± 2.7	31.2 ± 2.6	31.2 ± 2.7	0.5 ± 0.9	NS
BF (%)	Active	30.2 ± 2.7	–	–	27.9 ± 2.5	2.3 ± 1.5	0.01
	Placebo	29.7 ± 2.5	–	–	29.0 ± 2.6	0.7 ± 0.6	NS

^aP-values are for the change from week 0 to week 12.

Values are means ± SD.

NS, not significant.

with single individuals and may not be optimal since formal dose–response studies have not been carried out with the product. The excellent tolerability of the product

suggests that it could provide a useful alternative for people who wish to lose weight, but larger scale studies with an optimal dose are needed to assess this.

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