

**CLINICAL TRIAL ON THE EFFECTS OF
CONSUMPTION OF NATURAL SWEETENERS
DERIVED FROM THE STEVIA PLANT ON PEOPLE
WITH METABOLIC SYNDROME**

**IN CONJUNCTION WITH THE ENDOCRINOLOGY/METABOLISM
AND DIABETES UNIT OF THE “EVGENIDEIO CLINIC”**

Objective: a) To investigate the effect of consuming food from the **Sweet & Balance range containing natural sweetener from stevia plant extracts** and with a low Glycemic Index on improving Metabolic Syndrome Parameters and parameters related to cardiovascular disease and Diabetes mellitus type 2 which lead to Metabolic Syndrome. b) to undertake a study on the safety of long-term consumption (3 months) of food from the **Sweet & Balance range** by monitoring biochemical markers of renal and hepatic function.

Subjects: 42 subjects (16 men, 26 women), age 20-60 with metabolic syndrome and pre-diabetes were studied.

Products: The products tested in this study were as follows: Chocolate with orange filling, Milk chocolate with strawberry filling, with praline filling and with cappuccino filling, Milk Chocolate with almonds, Chocolate drink, Chocolate mousse and Caramel cream.

Method: subjects were randomly separated into two groups. One group of 22 people (**the Sweet & Balance Group**) followed a balanced, low calorie diet programme. **Sweet & Balance** products were included in the diet **four times a week**. The second group of 20 people (**the Control Group**) also followed a balanced diet programme for three months. The food products being tested were not included in the diet, but subjects in the Control Group were given the **opportunity to eat a sweet of their choice once a week**. Frequent dietary monitoring was conducted on both groups. During the initial assessment and after the three month long intervention, indicators linked to metabolic syndrome and chronic inflammation were measured. More specifically, the following parameters were studied: Cholesterol, Triglycerides, HDL, LDL, SGOT, AGPT, YGT, Glucose, Insulin, Uric acid, Urea, Creatinine, Potassium, Sodium, Calcium, Phosphorus, Albumin, Alkaline Phosphatase, TSH, FT4, HbA1c, hsCRP, Cortisol, Leptin, Antipodectin, ox-LDL, IL-6, suPAR, PAI-1, PEROX.

Results: Table 1 lists the basic parameters that were determined in the control group and the **Sweet & Balance** group before and after the end of the three-month intervention.

Table 1. Group measurement results

Parameters	Initial Control Group	Final Control Group		Initial Sweet & Balance	Final Sweet & Balance	
Insulin (mmol/mL)	21,542	17,13	p=0,92	17,025	13,827	p=0,178
Glucose (mmol/l)	6,0025	6,2245	p=0,225	109,60	105,73	p=0,148
Cholesterol	216,77	197,08	p=0,105	232,33	213,40	p=0,022
Triglycerides	140,08	129,08	p=0,321	157,47	137,07	p=0,333
ox-LDL - cholesterol	144,54	121,31	p=0,052	150,40	136,47	p=0,072
HDL cholesterol	41,85	49,85	p=0,002	50,59	49,53	p=0,68
ox-LDL	64,969	76,889	p=0,016	119,365	89,355	p=0,016
BMI (kg/m ²)	36,282	34,6815	p=0,329	37,5898	35,6227	p=0
Leptin	35,112	37,643	p=0,263	75,533	56,647	p=0,071
Systolic Blood Pressure (SBP)	143,31	136,54	p=0,02	149,00	130,47	p=0
Diastolic Blood Pressure (DBP)	92,69	86,54	p=0,176	95,00	83,00	p=0

The statistical analysis showed that in the control group there was a statistically significant decrease in BMI ($p = 0.01$) and Systolic BP ($p = 0.02$) after dietary intervention. In the **Sweet & Balance** group there was a significant reduction in total cholesterol ($p = 0.022$), ox-LDL ($p = 0.016$), BMI ($p < 0.001$), systolic BP ($p < 0.001$) and diastolic BP ($p < 0.001$), after dietary intervention which also included consumption of Sweet & Balance products 4 times weekly. LDL ($p = 0.072$) and leptin ($p = 0.071$) also showed a borderline significant reduction ($p < 0.1$). Comparing the parameter changes before and after intervention in the two groups (**Sweet & Balance Group** and **Control Group**), it appeared the parameters where changes varied considerably between the two groups were the following: ox-LDL which was reduced significantly more in the group which received **Sweet & Balance** products ($p = 0.010$), Systolic BP ($p = 0.003$), fasting glucose ($p = 0.058$) and leptin ($p = 0.054$).

Conclusions: The consumption of **Sweet & Balance** products containing extracts from the stevia plant during dietary intervention in patients with metabolic syndrome is completely safe with respect to its action on renal and hepatic function (indeed it reduces transaminases), leads to **weight loss**, significantly reduces BMI, blood pressure (systolic and diastolic) and bad cholesterol. Comparing the parameter changes measured before and after intervention in the two groups it appeared the parameters where changes varied considerably between the two groups (**Sweet & Balance Group** and **Control Group**), were the following: ox-LDL (which was reduced significantly more in the group which received stevia), Systolic BP, fasting glucose and leptin. Products containing natural sweetener from the stevia plant extracts are high added value products as introducing these foods to the oligothermal diet of patients with metabolic syndrome can lead to further decrease in blood pressure, fasting glucose, ox-LDL and leptin, which are key factors for increased risk of atherosclerosis and Diabetes mellitus type 2.