

HIPOGLYC – An hypoglycemic product based on indigenous antidiabetic plant extract for the treatment of type 2 diabetes

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Introduction and Aims. Romania is a country with an old and strong tradition in using plant products for the treatment of many diseases, including type 2 diabetes. From the 25 plants used for centuries in the treatment of diab.0/[‘tttttgg66es, we selected 6 indigenous species: *Morus alba*, *Vaccinum myrtillus L*, *Galega Officinalis*, *Agrimonia Empatoria*, *Trigonella Faenum-Graec* and *Phaseolus vulgaris sine Sinebus*. We aimed to use an original type of extraction and association in capsules of 500 mg. The aim of this study was to assess the tolerability and efficacy of this extract in patients with type 2 diabetes.

Patients and methods. We performed a double blind placebo controlled trial in 33 type 2 diabetes patients, 18 (54.5%) females and 15 (45.5%) males, registered in the National Institute of Diabetes "NC Paulescu", Bucharest. A signed informed consent has been obtained from all participants. Patients were randomized in a 1:2 ratio for placebo : active compound. This preliminary report presents the data following baseline (V1) and one month visits (V2). A crossover was done at V2 but the results after the switch were not yet available for this analysis. The age, sex, disease duration, body mass index (BMI), waist circumference (WC), fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), total, LDL and HDL cholesterol (TC/LDLc/HDLc), triglycerides (TG), liver enzymes (AST/ALT), uric acid, urea and creatinine were available for analysis.

Results. Despite a higher age (64.18 ± 4.58) for the placebo group (11 subjects) comparing with the active group (47.68 ± 14.71 , $p < 0.05$ - 22 subjects), there were no significant ($p > 0.05$) differences between the two groups for the mean disease duration (1.86 ± 3.34 years), BMI (31.83 ± 4.88 Kg/m²), WC (109 ± 16.7 cm), FPG (151 ± 38.6 mg/dl), HbA1c ($7.69 \pm 1.44\%$), TC (206.66 ± 82.4 mg/dl), LDLc (127.67 ± 37.5 mg/dl), HDLc (46 ± 11.94 mg/dl), TG (222.03 ± 324.49 mg/dl), AST (23.52 ± 6.29 U/L), ALT (31.47 ± 13.46 U/L), uric acid (5.23 ± 1.4 mg/dl), urea (36.18 ± 10.6 mg/dl) and creatinine (0.85 ± 0.2 mg/dl). Plasma samples at each visit were stored for the determination of insulin, proinsulin, amylin and adiponectin. All the frozen samples will be analyzed at the end of the study. At V1, the placebo group had a significant reduction in HDLc with 4.49 ± 4.67 mg/dl ($p < 0.05$) and no significant changes in all the other parameters; the active group had a significant reduction in HbA1c with $0.75 \pm 1.64\%$ ($p < 0.05$), in TC with 39.6 ± 82.85 mg/dl ($p < 0.05$) and LDLc with 10 ± 28.52 mg/dl ($p < 0.05$), a somewhat borderline reduction in FPG with 17.91 ± 40.5 mg/dl ($p = 0.051$) and no significant changes for all other parameters. No side effects were recorded.

Conclusions. Our preliminary data show that the plants used in our study, selected according to their previously established active content and processed in a specific manner, are active as regulators for both blood glucose and plasma lipids. The target of the active compounds from our extract might interfere with the various diabetogenic mechanisms, acting not only on the beta cells but also on the insulin dependent cells. The study was supported by the CEEEX 112/2006 grant offered by the Romanian Academy of Medical Sciences.