Phase I clinical trial to evaluate TOTUM-63, a botanical complex for managing prediabetes

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The IDF estimates that the number of individuals with prediabetes will increase to 463 million (8.6% of the population) by 2040. According to the ADA, 86 million Americans aged 20 years or older are prediabetic. We have developed an innovative botanical complex (BC) that aims to reverse prediabetes and to prevent each dysfunction and/or its consequences independently. The ability of the BC to control fasting glycemia, HbA1c, insulin sensitivity, serum and hepatic triglycerides, and weight gain through a specific effect on fat mass has been demonstrated in animal models (stubs, C57Bl/6 high-fat diet, C57Bl/6/NRI and Syrian hamster normal diet).

The present study is a controlled, cross-over, sequential, monocenter, prospective, pilot tolerance study. The study was conducted in accordance with the ethical principles set forth in the Declaration of Helsinki, 1964, as amended in Edinburgh in October 2000 and Somerville, West South, Australia, 1996. This study was conducted in conformance with good clinical practice (GCP). Each participant personally and freely gave his/her informed consent before being enrolled in the study.

The experimental design used intra-individual comparison in the same group of subjects. Each subject included participated to 2 periods of 4 weeks during which two different doses of the botanical complex were administered daily (period 1 (V1 to V2): 2.5g per day and period 2 (V3 to V4): 5g per day). Between these two periods, there were a 2-week washout period (V2 to V3). Blood and urine samples were taken, an electronic anthropometric examination was conducted, and the subject’s heart rate, blood pressure, body weight and waist size measured during visits 0, 2, 3 and 4 (V0, V2, V3, V4). Finally, two oral carbohydrate tolerance tests were carried out during visits 3 and 4 (V3 and V4).

The primary evaluation criterion was the good tolerability of subjects to two doses of the botanical complex. Totum-63. Secondary evaluation criteria was blood glucose and insulin kinetics during an oral carbohydrate tolerance test.

**RESULTS**

**ADVERSE EVENTS**

None of the adverse event observed during the study in some patients (head ache, cold, low back pain, flattening,...) were classified as serious and related to the botanical complex. Totum-63 could not be improved, as shown by the reduced area under the curve and maximal concentration for insulin (AUC and Cmax respectively).

**CARBOHYDRATE TOLERANCE TEST**

After 4 weeks of supplementation with Totum-63 (5g/day), insulin response during oral carbohydrate tolerance test was lowered, as shown by the reduced area under the curve and maximal concentration for insulin (AUC and Cmax respectively).