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

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

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ABSTRACT

The objective of the present study is to objectify the good tolerability of the botanical complex TOTUM-63 on different blood, urine and hemodynamic biological parameters, and during an oral carbohydrate tolerance test in overweight subjects.

SUBJECTS

The study took place in the Clinical Pharmacology Centre, CHU Clermont-Ferrand. The inclusion criteria for inclusion were male subjects between 45 and 65 years, with BMI between 25 and 30 kg/m², stable weight, physical activity level and eating habits for the two doses tested. In addition, BC did not induce an increase in insulinemia AUC (V4:3286±624 mg/ml/min) compared to the two doses tested. Moreover, the results observed at V4 (after the 4 weeks with 5g/day of TOTUM-63 supplementation) indicate that this dose of TOTUM-63 might improve insulin-sensitivity during oral carbohydrate tolerance test. TOTUM-63 is a well-tolerated product. Moreover, the results observed at V4 (after the 4 weeks with 5g/day of TOTUM-63 supplementation) indicate that this dose of TOTUM-63 might improve insulin-sensitivity during oral carbohydrate tolerance test. Taken together, TOTUM-63 is a well-tolerated candidate to pre-diabetes management. Well-conducted phase II clinical trial in targeted populations should be conducted to confirm the clear proof of concept brought by this first study in humans.

REFERENCES


Figure 4: Insulin sensitivity index (SI) during carbohydrate tolerance test: SI was calculated according to the following formula: [360*glucose (mg/dL)/insulin (µU/ml)]

GLUCOSE DURING ORAL 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, Fig. 4).

Figure 5: Insulin response during carbohydrate tolerance test: TOTUM-63 induced a decrease in the insulinemic peak (Cmax, P<0.05).