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

P. Sirvent, M. Bargetto, V. Chavanelle, Nicolas Macian, Sylvia Boulliau, Gilles Ducheix, Christian Dualé, Claude Dubray, Gisèle Pickering, S L Peltier

To cite this version:

P. Sirvent, M. Bargetto, V. Chavanelle, Nicolas Macian, Sylvia Boulliau, et al.. Phase I clinical trial to evaluate TOTUM-63, a botanical complex for managing prediabetes. 77th Scientific Sessions of American Diabetes Association, Jun 2017, San Diego, United States. hal-01682304

HAL Id: hal-01682304
https://hal-clermont-univ.archives-ouvertes.fr/hal-01682304
Submitted on 12 Jan 2018

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L’archive ouverte pluridisciplinaire HAL, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d’enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.
The phase I clinical trial to evaluate TOTUM-63, a botanical complex for managing prediabetes

Sirent P1, Burgetto M1, Chavannelle V2, Macian N1, Boulliau S1, Ducheix G1, Duale C1, Dubray C1, Pickering G1, Pelletier SL1

Laboratoire AME2P, Université Clermont-Auvergne, France, 2VALBIOTIS, La Rochelle, France, 3Centre d’Investigation Clinique, Clermont-Ferrand, France

ABSTRACT

The IDF estimates that the number of individuals with prediabetes in the world will increase with TOTUM-63 (5g/day), glucose tolerance during oral carbohydrate tolerance test was improved, as shown by the reduced area under the curve (AUC) and maximum concentration for insulin (AUC and Cmax respectively).

BACKGROUND

Worldwide, the number of people with type 2 diabetes is estimated at nearly 500 million1. The estimated total cost of healthcare in the United States and in Europe as a result of type 2 diabetes was 456 billion in 2015. According to the World Health Organization, prediabetes is defined by a fasting glycaemia between 6.1 and 7.0 mmol/L and/or glycaemia between 7.8 and 11.1 mmol/L, two hours after a standardised breakfast. From the American Diabetes Association, potentially 70% of prediabetics will develop diabetes2. Different studies have shown that implementing diet and lifestyle changes, and even anti-diabetic treatments, can decrease the risk of prediabetics developing diabetes3,4. It is thus possible to regress from prediabetes back to normoglycemia (3). However, even if diet and lifestyle changes are effective, patients rarely adhere to them on the long term. The use of food supplements in addition to lifestyle changes to prevent type 2 diabetes, in particular for prediabetics, has already been considered. Nevertheless, no food supplement has yet demonstrated a clearly relevant adverse event has been reported. Considering safety conclusions TOTUM-63 is a well-tolerated product. TOTUM-63 is a very promising candidate to oral carbohydrate tolerance test. Taken together, TOTUM-63 is a well-tolerated product. We conclude that this study results support the further development of TOTUM-63 as a potential therapeutic agent for the management of prediabetes.

SUBJECTS

The trial 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 three months before the start of the study. The primary endpoint was the improvement of glucose tolerance during oral carbohydrate tolerance test. In addition, TOTUM-63 has shown very good tolerance.

RESULTS

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.

Methods

The trial was conducted following the Declaration of Helsinki, 1964, as amended in Edinburgh in October 2000 and Somerville West, South Africa, 2016. 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 TOTUM-63 were used (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 electrocardiogram recorded, and the subject's heart rate, blood pressure, body weight and waist size measured during visits 0, 2, 3 and 4 (V0, V2, V3 and V4). Finally, two oral carbohydrate tolerance tests were carried out during visits 3 and 4 (V3 to 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.

Carbohydrate tolerance test

The primary evaluation criterion was the good tolerability of subjects to two doses of the botanical complex TOTUM-63. This good tolerability was characterized by stable biological, hemodynamic and anthropometric parameters following administration of TOTUM-63. No clinically relevant adverse event has been reported. Considering safety conclusions 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 very promising 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


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

Sirent P1, Burgetto M1, Chavannelle V2, Macian N1, Boulliau S1, Ducheix G1, Duale C1, Dubray C1, Pickering G1, Pelletier SL1

Laboratoire AME2P, Université Clermont-Auvergne, France, 2VALBIOTIS, La Rochelle, France, 3Centre d’Investigation Clinique, Clermont-Ferrand, France

ABSTRACT

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

BACKGROUND

Worldwide, the number of people with type 2 diabetes is estimated at nearly 500 million1. The estimated total cost of healthcare in the United States and in Europe as a result of type 2 diabetes was 456 billion in 2015. According to the World Health Organization, prediabetes is defined by a fasting glycaemia between 6.1 and 7.0 mmol/L and/or glycaemia between 7.8 and 11.1 mmol/L, two hours after a standardised breakfast. From the American Diabetes Association, potentially 70% of prediabetics will develop diabetes2. Different studies have shown that implementing diet and lifestyle changes, and even anti-diabetic treatments, can decrease the risk of prediabetics developing diabetes3,4. It is thus possible to regress from prediabetes back to normoglycemia (3). However, even if diet and lifestyle changes are effective, patients rarely adhere to them on the long term. The use of food supplements in addition to lifestyle changes to prevent type 2 diabetes, in particular for prediabetics, has already been considered. Nevertheless, no food supplement has yet demonstrated a clearly relevant adverse event has been reported. Considering safety conclusions TOTUM-63 is a well-tolerated product. TOTUM-63 is a very promising candidate to oral carbohydrate tolerance test. Taken together, TOTUM-63 is a well-tolerated product. We conclude that this study results support the further development of TOTUM-63 as a potential therapeutic agent for the management of prediabetes.

SUBJECTS

The trial 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 three months before the start of the study. The primary endpoint was the improvement of glucose tolerance during oral carbohydrate tolerance test. In addition, TOTUM-63 has shown very good tolerance.

RESULTS

The primary evaluation criterion was the good tolerability of subjects to two doses of the botanical complex TOTUM-63. This good tolerability was characterized by stable biological, hemodynamic and anthropometric parameters following administration of TOTUM-63. No clinically relevant adverse event has been reported. Considering safety conclusions 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 very promising 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


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

Sirent P1, Burgetto M1, Chavannelle V2, Macian N1, Boulliau S1, Ducheix G1, Duale C1, Dubray C1, Pickering G1, Pelletier SL1

Laboratoire AME2P, Université Clermont-Auvergne, France, 2VALBIOTIS, La Rochelle, France, 3Centre d’Investigation Clinique, Clermont-Ferrand, France

ABSTRACT

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