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Intestinimonas Butyriciproducens As A New Preventive Therapy For Type 2 Diabetes: a Proof Of Concept Randomized Controlled Trial

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Background. The incidence of type 2 Diabetes Mellitus (T2D) is increasing worldwide. Prevention is possible by changing lifestyle but it's not effective alone in real life, due to poor compliance over time. New strategies are necessary, mostly for high-risk individuals. Therapeutic microbiology is a further proposed target, and butyrate-producing bacteria can improve metabolic parameters in obese patients. Our study aims to evaluate the effect of *Intestinimonas butyriciproducens* as a preventive therapy for T2D in prediabetes thanks to its effects in decreasing Advanced Glycation End Products (AGEs), converting sugars and proteins in butyrate, and increasing insulin sensitivity.Methods. The trial is a double-blind, randomized, placebo-controlled (phase 1) and open-label pilot study with two different doses (phase 2) of 26 weeks. *I. butyriciproducens* (10^5 CFU/day) or placebo were given for 12 weeks, then subjects in placebo will start the treatment (10^5 CFU/day), and the other group will increase the dose (10^8 CFU/day) for 14 weeks. Overweight or obese patients with impaired fasting glucose (IFG) or impaired glucose tolerance (IGT) were included. Patients were assessed for clinical, biochemical, and microbiota parameters at the time of recruitment (V1), after phase 1 (V7) and phase 2 (V10), during which the eating and lifestyle habits were also evaluated. No dietary advice was given. Results. Nineteen have completed the study. Treated patients during the first phase had a significant improvement in glucose-insulin metabolism demonstrated through the HOMA Disposition Index (p= 0.0075). Lipid profile also ameliorates in patients treated at a low dose and then at a high dose, particularly decreasing triglycerides (phase 1: p= 0.0212; phase 2: p= 0.0261). The weight and BMI of patients were stable throughout the period of study. Data from Flash glucose Monitoring (FGM) show a more stable glucose, mainly at the end of the study. Serum AGE concentrations showed a trend towards a decrease in treated patients, whereas IL-10 slowly increased without changes in IL-6 and IL-17.Lastly, 10 out of 19 patients after 26 weeks of treatment had a remission in IFG or IGT (52.6%). Conclusions. *Intestinimonas butyriciproducens* seems to improve insulin sensitivity and triglycerides in treated patients. *Intestinimonas butyriciproducens* could be a new strategy in the work-up of T2D prevention.

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