

Project title:

Novel Intestinal Microbiota-based Medicine for Preventing Type 2 Diabetes Mellitus

Acronym/working title:

DM-prevent

Principal Investigator

Prof. Falvia Prodam, DISS UPO, 28100 Novara; flavia.prodam@med.uniupo.it

Prof. Gianluca Aimaretti, DIMET UPO; SCDU Endocrinologia, AOU Maggiore della Carità, 28100 Novara gianluca.aimaretti@med.uniupo.it

Registration number of the Ethical approval

Comitato Etico Interaziendale di Novara N° 167/19

Project summary

As the prevalence of T2DM is constantly increasing and the current therapeutic options for the prevention of this disease developed into a microbiotic product (MMP) for T2DM prevention in high-risk individuals. The therapeutics activity of this bacterium is based on the 3-fold mechanism of action:

- Decrease the production of Advanced Glycation End Products (AGEs) that are associated with diabetes complications

- Converts sugar and protein in butyrate, a short chain fatty acid (SCFA) with beneficial health effects in metabolic diseases

- Restores insulin sensitivity, which is reduced in prediabetes.

This study aims to assess the effect of probiotics containing *Intestinimonas butyriciproducens* in adults with prediabetes. The purpose is to determine the efficacy of a dose of the probiotic product (*Intestinimonas*) on insulin sensitivity in a target group of prediabetic individuals. In particular, we want to evaluate whether the probiotic selected doses are able to improve the insulin sensitivity, the response to the oral glucose tolerance test (OGTT) and whether it is able to modulate the microbiota composition of the individuals under analysis.

Duration of Study

Total duration of the study: 1 year Study start: March 2021 Study end: March 2022

Total number of participants involved:

26

Biological samples collected:

- ✔ serum
- ✔ plasma sodium-citrate
- ✔ plasma EDTA

- plasma lithium-heparin
- ✓ buffy coat
- 🖌 urine