

**Project title:****SUSCEPTIBILITY TO INFECTIOUS DISEASES IN OBESITY: AN ENDOCRINE, TRANSLATIONAL, AND SOCIOLOGICAL EVALUATION****Acronym/working title:****SIDERALE****Principal Investigator**

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**Registration number of the Ethical approval**

Comitato Etico: prot. 00026740

**Project summary**

This project aims to provide new information regarding the onset of infectious disorders in patients with obesity and type 2 diabetes (T2D) taking into consideration the complex interaction between the endocrine system, the chronobiology, gut microbiota, and the obesity determinants. In particular, the project focuses on:

- 1) Investigate the effects of a Mediterranean dietary regimen supplemented with 1mg of melatonin on the infectious disorders.
- 2) Investigate the correlation between the gut and the oral microbiota and infectious disorders in patients with T2D and obesity.
- 3) The relationship between environmental conditions and lifestyle through specific questionnaires and finally the possible impact on the National Health System of our study.

This is a prospective, interventional, non-pharmacological, multicentre, no-profit clinical study. 20 subjects will be enrolled at the SCU of Endocrinology at the Maggiore Hospital della Carità of Novara. Subjects will have the following characteristics: aged between 15-65 years, BMI 30-40 kg/m<sup>2</sup>, and T2DM.

The study includes different time points:

- 1) Time 0 (T0) that corresponds to the enrolment. Following the understanding and signing informed consent, patients will be subjected to anthropometric measurements (weight, height, waist and hip circumference, BMI calculation, and plicometry) and various questionnaires to assess their eating habits, circadian rhythm, and sociological characteristics.
- 2) Time 1 (T1): patients will be blood-sampled to assess clinical practice parameters. At the same time, serum and plasma will be stored for subsequent analysis of inflammatory biomarkers. Blood samples will be taken (at 8.30 am and 4.30 pm) for PBMC isolation, as well as stool and saliva samples will be stored for subsequent analysis of the gut and oral microbiota. At time 1 patients will be instructed in the Mediterranean diet.
- 3) Time 2 (12 weeks after diet) (T2): patients will be subjected to blood sampling and collection as time 1. Moreover, anthropometrical parameters will be measured as time 0. From this time patients start to be administered with melatonin 1mg.
- 4) Time 3 (after 12 weeks of diet + melatonin) (T3) patients will be subjected to the same measurements of time 1 and 0.

**Duration of Study***Total duration of the study: 36 months**Study start: 01/01/2025**Study end: 01/01/2027***Total number of participants involved:****20**



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**Samples collected:**

- ✓ Buffy coat
- ✓ Plasma EDTA
- ✓ Plasma lithium-heparin
- ✓ Serum
- ✓ Saliva
- ✓ Feces