



“Impact of melatonin, food timing and receptor gene variant on type 2 diabetes risk”

Main researcher: Marta Garaulet Aza

Identifier: NCT03036592

Date: 09/01/2016



Code:

Date:

INFORMED CONSENT

Title of the clinical trial: "MTNR1B SNP*Food Timing Interaction on Glucose Control in a Late Eater Mediterranean Population"

clinical trial number: NCT03036592

Study directors: Dr. Marta Garaulet Aza.

The aim of the study is to investigate the role of melatonin and the gene variant of its receptor (MTNR1B rs10830963) in the metabolism of glucose, with the possible relevance in the diagnosis of type 2 diabetes (DT2), its prevention and treatment. The project will address an important issue to demonstrate whether melatonin in humans interferes with the physiological response to food intake, possibly triggering carbohydrate intolerance, and whether this effect is more potent in the carriers of the MTNR1B SNP risk compared with non-carriers.

To do this, the following study protocol will be made to each one of the participants:

Assessment:

- Collection of personal data (name, age).
- Measurement of weight, height, waist and hip circumferences, impedance.
- Evaluation of dietary intake by means of a 24-hour dietary reminder from the previous day.
- Weekly intake record (7 days), intake and sleep schedules, and record of the light to which they are exposed.
- Performance of 2 glucose tolerance tests (OGTT) (early and late).
- Extraction of blood samples for OGTT.
- Test habits and lifestyles (Emotional dining room, Physical activity, Sleep quality and Chronotype).

After having been informed of the nature of the study and the procedures that will be directed by Dr. Marta Garaulet, I agree to voluntarily participate in it, giving my consent for your data to be used for the purpose described above, to cover the objectives of the Research Project entitled "Impact of melatonin, meal time and the gene variant of melatonin receptor on type 2 diabetes", funded by the Ministry of Science and Innovation (SAF2014-52480-R).

I have also been informed that my personal data will be protected and included in a file that must be submitted to and with the guarantees of law 15/1999 of December 13.

I have also been informed that I can leave my participation in the study at any time without giving explanations and without causing any harm to me.

From this study my specific benefits will be to know if a late dinner, in which there are foods rich in carbohydrates, can affect my health in relation to the metabolism of glucose (increase in blood sugar), also I have the right to know my gene variant of the melatonin receptor. I am free to decide not to know this information.

Taking this into consideration, I GRANT my CONSENT to this extraction to take place and be used to cover the objectives specified in the project.

Mr./Ms.:

The patient

DNI:

Murcia,/...../.....