

BENEFICIAL EFFECT OF A LOW FODMAPs DIET IN DIFFERENT GASTROINTESTINAL DISORDERS

Naples, Italy

July 20, 2017

INFORMED CONSENT FORM FOR THE PATIENT

AIM OF THE STUDY:

The aim of this study is to evaluate the clinical impact of a low-diet in FODMAPs in patients with irritable bowel syndrome (IBS), celiac disease (CD) on gluten-free diet (GFD) and inflammatory bowel diseases (IBD) in remission. In particular:

1. Evaluate the presence and type of symptoms through a questionnaire at the time of enrollment and after three months of low-dose FODMAPs in three different patient groups (IBS, CD and IBD).
2. Evaluate the quality of life of the three groups of patients through different questionnaires (specific for each group) before and after dietary changes.

The study, approved by the Ethics Committee of the University "Federico II" in Naples, lasts 6 months and involves the participation of about 120 patients.

Before deciding whether to take part in the study, the participants have all the time to inquire and confront themselves with a family member or other trusted physician. In addition, the participants can withdraw from the study at any time without the need to state the reasons and /or justification and any penalties or loss of benefits to which they are still entitled.

PROCEDURES:

Subjects' participation will be entirely voluntary. If subject decide to participate, he/she will be required to have a specific dietary regimen for your energy needs (calculated on the basis of BMI) and the content in FODMAPs, made in accordance with the reference food tables, for 12 weeks. Simple questionnaires will be administrated before starting the forementioned dietetic regimen, after a month of the beginning and three months later.

BENEFITS:

By participating in this study, the participants will benefit from the possible effectiveness of this diet in improving or resolving your symptoms. In addition, participants will give their contribution to scientific research in the medical field.

RISKS:

There are no risks associated with this study. In addition, any pharmacological therapies in progress will be maintained for the duration of the study.

COSTS AND COMPENSATION:

No compensation is payable for subjects' participation in the study.

Participants will have the right to change their mind and leave the study even if it has already begun.

Participants will be informed if interesting and health-related data will emerge.

QUESTIONS:

In case of question, please contact Prof. Fabiana Castiglione: 081-7463849.

Name _____ Surname _____

Address _____

I have read and understood all the information that the physicians have provided to me. I had the opportunity to discuss, ask questions and receive comprehensive answers from the researchers involved in the study. I am freely agree to take part in the study titled "BENEFICIAL EFFECT OF A LOW FODMAPs DIET IN DIFFERENT GASTROINTESTINAL DISORDERS"

I understand that participation in this study includes:

- the prescription of a dietary regimen
- the administration of some questionnaires after one month and three months after the beginning of the diet.

I have read and understood what risks and benefits are related to the study.

I am aware that my participation is completely free and voluntary and that I can withdraw from the study at any time without the need to state the reasons and / or justification and any penalties or loss of benefits to which it is still entitled.

I understand that the doctor and regulatory authorities will have direct access to my original medical records and that all clinical, biological, and demographic data will be anonymously spread.

The Ethics Committee of the University of Naples Federico II will monitor the correct application of the rules of good conduct in the field of scientific research.

I understand that a copy of this informed consent will be given to me and another will be filed in a closed envelope under the responsibility of the scientific manager.

Naples, _____

Patient's signature

Investigator's signature