Informed Consent 28/11/2013

INFORMATION COMPLET FOR PATIENTS:

Eat well, grow better: today sardine

Research project: A dietary intervention study to investigate the beneficial effects of a diet rich in sardine protein on the incidence of type 2 diabetes mellitus in an elderly population.

Principal Investigator Dr. Ramon Gomis

Service: Diabetes and Obesity Laboratory- IDIBAPS, Endocrinology and Nutrition Service-Hospital Clínic

Targets:
We request your participation in this research project, whose main objective is to deepen in the knowledge of the dietary factors that can help to improve the prevention of the appearance of type 2 diabetes in a population of elderly people at risk to develop the disease.

Participation in the study:
The participation in the study is completely voluntary and it is possible to leave the study at any time without this involving a change in your future medical attention or in your relationship with the doctor who usually cares for it.
Before starting the study, the doctor will ask about their pathological history in order to know if they meet the inclusion criteria in the study and assess their eligibility.

Benefits:
It is possible that you do not get a direct benefit from your participation in this study. However, the identification of foods (such as sardines) capable of providing a direct benefit in the prevention of type 2 diabetes could benefit in the future from other patients at high risk of suffering from it and contributing to an improvement in the prevention and treatment of this disease.

Study procedures:
The study will have a total duration of 13 months, and is structured in several visits as explained below.

- Visit (-1)

The researchers will assess their eligibility to participate in the study. If you fulfill all the criteria to be able to participate, the whole study will be explained to you and, if you agree to participate, you must sign informed consent. Later, a detailed medical history and exploration will be made and the nutrition intervention that will follow during the 12 months will be assigned randomly. It may be a normocaloric diet with a higher content in sardines (sardine group), or a Mediterranean normocaloric diet (control group).
For this, you will have a team of nutritionists who will explain to you how to properly perform the diet that has been assigned to you. In the 4 weeks after the screening visit, you will receive a nutrition education with group sessions. Finalized this month, you will evaluate your good understanding of the diet. It is very important that each day do the diet that has been awarded.
Good compliance is crucial to evaluate the possible beneficial effect of sardine in preventing the incidence of type 2 diabetes. A 2-week visit will be scheduled to be followed and a sample of Feces (a special pot will be given to save it).

- First visit (month 0: start of the study)

Blood samples will be extracted and a sample of feces must be taken. For this reason, you will have to go to the center in a while (8 hours before leaving). You will have to fill out some questionnaires about your state of health in general, about the physical activity you practice and about your sound quality. In this visit, patients will receive sterile material for the collection of fecal samples that they will have to carry on visit 4.

- Messually

Monthly, you will be called on the phone to know if you are doing well with the diet and know if this diet produces any harmful effect on your health. You can schedule a visit with a nurse or doctor in relation to this call.

- Visit the 4th month

Blood samples will be extracted and a sample of feces must be taken. For this reason, you will have to go to the center in a while (8 hours before leaving). Adverse clinical effects will be recorded. If necessary, a detailed physical examination will be performed. The adherence to the diet will be considered and the FFQ questionnaire will be carried out. The nutritionist will control the correct understanding and follow-up of dietetic education of patients. In addition, it will also encourage the patient to adhere to the diet and evaluate any specific difficulty related to the intervention diet.

- Visit at 8 months

Blood samples are extracted. For this reason, you will have to go to the center in a while (8 hours before leaving). The adherence to the diet will be considered and the FFQ questionnaire will be carried out. The nutritionist will control the correct understanding and follow-up of dietetic education of patients. In addition, it will encourage the patient to adhere to the diet and evaluate any specific difficulty related to the intervention diet. In this visit, patients will receive sterile material for the collection of fecal samples that they should carry on visit 12.

- Visit at 12 months: final visit

The clinical data questionnaire and the adverse clinical effects will be recorded. For this reason, you will have to go to the center in a while (8 hours before leaving). There will be a physical exploration. Blood samples will also be taken for laboratory determinations and fecal samples will be collected. The concomitant medication will be registered. The Euro Qol, FFQ, physical activity and one on the quality of the sound will be carried out. During the visit, the nutritionist will control the patient's 4-day diet registry.

Discomforts and possible risks:
Blood sampling can cause a burning sensation at the point where the needle is inserted into the skin and cause a small hematoma or a slight infection that disappears within a few days. More rarely, dizziness can occur when blood is removed. The rest of the tests are not invasive. In principle, tracking the diet rich in sardines should not have any harmful effect on your health.

Site of the analysis:
The analyzes will be carried out at the Hospital Clínic de Barcelona.

Right to revoke consent:
Your participation in the study is totally voluntary, and if you choose not to participate you will receive all the medical care you need and the relationship with the medical team that will be treated will not be affected.

At any time during the study, you can voluntarily decide to stop participating in it, without this decision affecting your future relationship with the medical team and your future medical assistance.
However, doctors involved in the study may decide not to continue in the study in the event of:

- Outcome of cooperation or compliance with the diet for you.
- Apartition of serious illness.
- The own decision of the doctor who considers that the continuation in the study would not be appropriate for you

Implications of the information obtained in the study:
If you decide to participate in the study, it is possible that in the analysis of your biological samples you get information relevant to your health or that of your family. In addition to the analyzes carried out in the context of the present study, samples will be stored as a collection of the IDIBAPS Diabetes and Obesity Laboratory, which could be used for future biomedical research studies, always under strict anonymity control and of ethical principles.
In accordance with current legislation, you have the right to be informed of the data obtained during the course of the study. If you want to know the information relevant to your health, get informed by your doctor about the implications this information may have for you and your family. This information will be communicated to you if you wish; In case you prefer not to be informed, your decision will be respected.
In accordance with Law 15/1999 on the Protection of Personal Data, the personal data obtained will be necessary to cover the purposes of the study. In the reports of the study, its name will appear, and its identity will not be revealed to any person except to fulfill the purpose of the study, and in case of medical urgency or legal requirement.
Any personal information that can be identifiable will be preserved by computerized methods under security conditions for the Hospital Clínic. Access to this information will be restricted to the Hospital Clínic staff designated for the purpose or to other authorized personnel who will be obligated to maintain the confidentiality of the information.
In accordance with the law in force, you have the right to access your personal data; Likewise, and if it is justified, you have the right to be rectified and canceled. If you wish, you will have to ask the doctor who attends this study.

Results of the analyzes
You will be informed of the results related to your metabolic control throughout the study.

Questions
If you have any questions or concerns regarding the study, do not hesitate to contact your doctor or team. They will be prepared to answer any questions or questions you may have during the study. If you have doubts about your rights as a participant in the study, ask your questions to the main investigators responsible for the study: Dr. Ramon Gomis, Dra. Silvia Canivell and / or Ms. Diana A. Diaz (telephone numbers: 93.3129411, 93.2275400 ext. 2910).

Informed Consent

I, …… (first and last name)

- I have read the information in the attached document that was delivered to me
- I agree to participate in the study
- I have been informed of all the details and I have answered all my doubts about it.
- I have been informed by Dr. .....
- I understand that my participation is voluntary
- I understand that I can leave the studio: or whenever I want, without having to give explanations, not affecting my medical care as a patient.
- I understand that my personal samples and all my data will be treated anonymously
- I understand that any residual material in the study will be destroyed

I freely give my consent to participate in this study:

_____ _____
Signature of the participant Date

_____ _____
Signature of the doctor Date