Hospital del Mar
Barcelona

**INFORMED CONSENT FOR THE PARTICIPANT**

**Version: 1.2 from 15th June 2024**

**TITLE FROM PROJECT: "** ***Randomized Study to Assess the Impact of Mediterranean Diet Optimization on Metabolic Profile, Immune Activation, and Cardiovascular Risk in People with HIV on ART*** **"**

**Title short:** **Study about the impact from the diet in the risk cardiovascular to the HIV**

**PRINCIPAL RESEARCHER: Dr. Robert Guerri Fernandez**
**Center/Hospital: Hospital of the Mar. Barcelona.**

**Introduction**

At Hospital del Mar, as in most hospitals, in addition to patient care, biomedicine research takes pleace. The purpose of this research is the progress in knowledge ranging from disease prevention to disease management itself. The development of a biomedical research project involves the collection of clinical data and, in some cases, performing a diagnostic tests or examination, and/or the extraction of biological samples for analysis, which together will help to better understand the disease under study.

Following the provisions of Law 14/2007, of July 3, on biomedical research and Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of rights digital, we request you to read carefully this document for information and informed consent, and we will clarify any doubts you may have. Our intention is that you receive the correct and sufficient information so that you can decide whether or not to participate in this study.

**Information specific of the Project from Research**

We appreciate your consideration of participating in the study to assess the impact of diet optimization in the metabolic profile, the immune-activation and the cardiovascular disease risk in people with HIV and on antiretroviral treatment (ART).

Cardiovascular risk is increased in patients with HIV due to classic risk factors such as lipid profile, in addition to immunoactivation associated with viral persistence, or to the ART. This study can help to know the effect from the Mediterranean diet on lipid levels and how to avoid a possible cardiovascular effect due to HIV infection and antiretroviral treatment.

Firstly, this study is randomized trial, that is, there is a group of participants who will be randomly assigned to the intervention group and another group who will continue with the same treatment and follow-up that it is was performing. All the participants will undergo a complete clinic history: including medical background, history infection HIV, treatment history

and questionnaires will be carried out on physical activity and dietary habits. None of these tests suppose a risk to your health nor will they change the therapeutic attitude towards your treatment. A simple no-harmful test that is called "pulse wave measurement" will be done to all participants. This test evaluates arterial stiffness and is a parameter that indirectly assesses cardiovascular risk. We will also obtain blood samples for complete analysis, study of cholesterol particles and the collection of serum and peripheral blood mononuclear cells (PBMCs). The blood material will be kept in the Musculoskeletal Research Unit of the IMIM for a period of 20 years under the responsibility of the principal investigator.
In the intervention group a series of visits with an **specialized nutritionist** that will evaluate the diet and will give instructions for improving it. Likewise, a scheduled follow-up will be carried out over a period of 6 months to evaluate the impact of the intervention.
In both groups a complete assessment will be done before (to the first visit) and to the none from 6 months.
Both groups will undergo non-invasive coronary artery **angiography using CT** (CCTA). CCTA is a non-invasive test that allows a detailed assessment of the coronary arteries, their anatomy and the presence of atherosclerotic plaques , as well as their location and severity. Currently, it can be performed with very low doses of radiation (around 3 mSv ) and requires intravenous contrast, with minimal complications. The test lasts a few minutes.
Patients will receive prior preparation by specialized nursing and heart rate monitoring, if necessary. CCTA has become a key test for the assessment of patients at cardiovascular risk.

The responsible of this one project it is **Dr. Robert Güerri-Fernandez** and both him and his team are linked to the Hospital del Mar, Barcelona and the Hospital del Mar Research Institute (former IMIM).
This project has state approved for Ethics Committee from Research with medicines of the Hospital del Mar.

Your participation in this study is completely voluntary and that it can withdraw at any time without this causing any harm to your health or attention at our center. We truly want to thank your acceptance to participate to the study. We acquire the commitment to try to cause you the least amount of disruption possible.

**In what will consist your participation?**
If you agree to participate, the first step will be that you will be randomly assigned to a group: either continue receiving the same treatment without none change or get into the intervention group in which you will be given an appointment with a nutritionist who will evaluate your diet and provide you with an intervention on how to optimize your diet and follow-up for 6 months.
In both groups you will undergo a complete assessment of the cardiovascular risk from blood test to wave pulse velocity to angiography using CT.

**Which benefits I will obtain from the mine participation to the study?**
The benefit direct that they will obtain the people that there participate it is that they will have a complete assessment of cardiovascular risk.

**Which disadvantages occasion the participation to the study?**
The disadvantages linked to your participation in the study are those related to the extraction from blood, that occasionally can produce one hematoma to the area from puncture. You may also feel dizzy. At the time of performing the CCTA, intravenous contrast will need to be administered. It is an iodine-based contrast (if you are allergic, the test cannot be performed). The infusion of the iodinated contrast may cause mild discomfort and a feeling of warmth that lasts a few seconds. Potential complications are minimal and may include: an allergic reaction , alteration of the creatinine filtrate which is usually temporary. The CCTA also involves exposure to ionizing radiation but the dose used for this scan is 3 times less than a normal chest scan . It is approximately equivalent to the radiation we receive in a year.

**What will happen with the samples biological leftovers and the information associated, one once the study is completed?**
Once the project is complete, we ask for your permission to keep the excess of your samples and associated information, that is, to keep the remaining sample after performing the different analyses planned in the study, and which may be used in future research projects related to infectious diseases such as those you were diagnosed with. In this case, all the remaining biological material would become part of the Biological Sample Bank of the Parc de Salut Mar ( MARBiobanc ). This sample bank is an authorized establishment that hosts organized collections of biological samples and information associated to the conditions and guarantees from quality and security as required by current legislation. The research will be carried out in facilities duly equipped for this purpose at PSMAR or other collaborating research institutions or those that officially request it from MARBiobanc .

If you agree to donate your excess blood sample to MARBiobanc , it will be stored for to future analyses in projects from research authorized for PSMAR Research Ethics Committee. Otherwise, the remaining sample will be destroyed at the end of the study.

**I will receive some compensation economic?**
No will perceive none benefit economic for the his/her participation to this one study

**How it is will protect the mine privacy?**
Both the researcher and the center will ensure that the confidentiality of the data is maintained. yours data personal collected during the study, in fulfillment both from the laws national data protection laws as well as European data protection laws:
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (GDPR) relative to the protection from the people physical for that ago to the treatment of personal data and the free movement of such data
- The Law Organic 3/2018 from 5 from December, from protection from data personal and digital rights guarantee (LOPDPGDD)

The data collected in this study will be used to answer the study questions. and the investigations related, beforementioned.

If you agree to participate in this study, the center and the researcher may reuse this data for other research projects, for the following research purposes: aspects related with the disease or process in study, determination from biomarkers of the disease, and the safety of the research procedure, respecting confidentiality at all times and guaranteeing compliance with current legislation.

Your data will be kept confidential at all times. During your participation in the study you will be identified by a code and neither the researcher nor the hospital will transfer none information that you can identify directly. The list that relates the identification code with the data that identifies you (name, surname, medical history number, etc.) is kept confidentially at the center, and will not be released.

Access to your personally identifiable information will be restricted to the study's principal investigator/collaborators, health authorities, the Research Ethics Committee with medicines ( CEIm ), when it need for check the data, the study procedures and compliance with standards. of good clinical practice; but always maintaining confidentiality. Your identity could be revealed in exceptional cases, such as situations of medical emergency for your health or legal requirement. The treatment, communication and transfer of personal data of all participants will comply with the provisions of the applicable regulations.

**Which rights they have how much to the yours data?**
Regarding your persona data, you have the following rights:
- You can ask in any moment which data they are saving (right access), who uses them and for what purpose; you can request a copy of your personal data for your own use.
- You can request receive one copy from the data personal provided for you to transmit them to other people (portability).
- You can correct your data personal provided and limit the use from data that is incorrect (right to rectification and deletion).
- You can oppose to the use of your data personal or restrict them (right of opposition).
- We remind you that in order to ensure the legitimacy of the research, there are certain restrictions on your rights to your personal data: Yes, choose to withdraw your consent to the processing of your data or to participate in the study. No, they will have the ability to erase the data that has been gathered up until that point. You're from Please be aware that participation in the study may be terminated if you choose to withdraw your consent to the processing of your data. Additionally, you might not have full access to your data. We will utilize as little information as we can to safeguard your rights.

Additionally, we advise you of your right to file a complaint with the Catalan Authority if you believe that any performance by the Promoter or the Center infringes upon your data protection rights. You can also get in touch with the center's data protection delegate at protecciodedades@imim.es.

Before sharing the study's findings with the general public who are not in the medical field, the researcher must publish the findings—whether favorable or unfavorable—in scholarly publications. The study participants will always remain anonymous through the use of confidentiality.

**Contact in case from doubts:**

Yes during the yours participation you have some doubt or you need obtain more information, please contact:

Principal Investigator: Dr. Robert Güerri-Fernández
Dept: HIV Division. Internal Medicine.
Phone number:+34 932483251
Schedule: from 9 am to 3pm

Hospital del Mar
Barcelona

**INFORMED CONSENT**

**Version: 1.2 from 15th June 2024**

**PROJECT TITLE: " Randomized study to evaluate the impact of dietary optimization in profile metabolic, the immunoactivation and the risk cardiovascular in population HIV " in TAR"**

**Title short: Study impact from the diet in the risk cardiovascular to the HIV** PRINCIPAL RESEARCHER: Dr. Robert Güerri Fernández

Centre/Hospital: Hospital del Mar. Barcelona

I... .....<<name and surnames of the participant>>

- ☐ I have read and understood the sheet of information and the appendix 1 that if has me delivered about the study.
- ☐ I have could to do questions about thestudy .
- ☐ I have received enough information about the study.
- ☐ I have spoken with .....<<name from the researcher>>
- ☐ I understand that the mine participation it is voluntary.
- ☐ I understand that me I can withdraw from the study: 1st When want. 2nd Without give explanations. 3rdWithout this having an impact on my medical care.

I will receive one copy signed and dated of this one sheet of information and consent informed

I consent to storage and use from the samples biological (remainders) leftovers from the blood tests that are performed) and the associated data in a collection for research purposes and is used in future research related to the disease under study, under the conditions explained in this information sheet .

☐ YES ☐ NO

I give the mine consent for to the conservation from the sample and from the data associated at MARBiobank .

☐ YES ☐ NO

I consent to to be contacted in the case from need more information or samples additional biological .

☐ YES ☐ NO Telephone or email from contact…….

Name and surnames of the participant: Name and surnames from the researcher:

_____ _____

Signature Signature

Date : __/__/_____ Date : __/__/_____

Hospital del Mar
Barcelona

**INFORMED CONSENT (copy for participant)**

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Signature Signature

Date : __/__/_____ Date : __/__/_____