PARTICIPANT INFORMATION SHEET

Project title: **Spanish national registry of sarcopenic obesity in patients with severe obesity.**

Acronym: SARCOBAR

Promoter: FSEEN_ Spanish Foundation of Endocrinology and Nutrition

This document is intended to provide you with information about a multicenter research study in which you are invited to participate. This study is being carried out at the [research center] and was approved by the Research Ethics Committee (REC) corresponding to its center and the Bellvitge University Hospital, which is the reference REC in carrying out this study.

If you decide to participate in it, you must receive personalized information from the researcher, read this document first and ask all the questions that are necessary to understand the details about it. If you wish, you can take the document, consult it with others, and take the time necessary to decide whether to participate or not.

Participation in this study is completely voluntary. You can decide not to participate, or, if you agree to do so, change your mind by withdrawing your consent at any time without obligation to give a reason. We assure you that this decision will not affect your relationship with your doctor or the healthcare professional to which you are entitled.

What is the purpose of the study?

The main objective of the study is to analyze body composition values (muscle and fat) and determine the presence of sarcopenia or low muscle mass in patients with severe obesity. Knowing these values is very important since they can serve as a reference to establish cut-off points for the diagnosis of sarcopenia in severe obesity and its relationship with associated diseases such as diabetes, hypertension, hypercholesterolemia, cardiovascular disease, osteoporosis, and poor quality of life. In those candidates for bariatric surgery, it will also allow us to determine the impact of the different surgical treatments for obesity (Sleeve gastrectomy, gastric bypass, duodenal switch/SADI-S) on function and muscle mass one year after surgery.

Why are they offering me to participate?

The selection of people invited to participate in a study depends on a series of criteria that are set at the beginning of the research and that are applied in the same way to all possible participants. You are invited to participate because you meet these criteria, which in summary are: Men and women between 18 and 65 years old. Diagnosis of obesity with a body mass index greater than or equal to 35 kg/m^2 with associated comorbidities or BMI >40 kg/m^2

It is expected that 480 people will participate, residing in different cities of Spain.

What does my participation consist of?

If you decide to participate in the study, your doctor specializing in Endocrinology and Nutrition will collect information on aspects related to your obesity, history of some diseases such as diabetes, hypertension, etc.

In addition, we will ask for your consent so that a telephone medical appointment service provided by the company STK Servicios Virtuales will call you to make an appointment to perform a densitometry in a vehicle located in [location within the municipality] and give you a reminder a few days before the established appointment. With this test we will look at your body's muscle to fat ratio. In addition, we will measure the strength of your hands and the time it takes to walk 6 meters.

STK Servicios Virtuales will process your data (name, surname, sex, age and municipality of residence) only for the purpose indicated above and will not share it or transfer it to any third party. Once STK Virtual Services has made an appointment with you to perform the densitometry and sends you a reminder a few days before the scheduled appointment, it will proceed to delete all your data that it has in its possession.

An analysis will also be performed to look at parameters related to glucose concentrations, insulin resistance, lipid profile, etc. and markers related to muscle function (myokines and inflammatory cytokines).

If you undergo bariatric surgery, one year after the operation the procedure will be repeated with densitometry and analysis.

The approximate time that participation in the study will take will be approximately one hour.

What risks or drawbacks does it have?

Bone densitometry is a test that uses x-rays. However, the radiation dose is very small and much lower than in routine x-ray tests (such as a chest or spine x-ray). It is a simple test and its approximate duration is 20 minutes.

Will I get any benefits for participating?

In this study, participants will not obtain any particular benefit from participating, however the knowledge generated could be useful for the future management of other patients in their situation. We will give you a copy of the densitometry to take to your doctor. We will not propose any treatment.

Will I receive the information obtained from the study?

If you wish, you will be provided with a summary of the overall results of the study once it is completed.

Will the results of this study be published?

The results of this study will be sent to scientific publications for dissemination, but no data that allows the identification of the participants will be transmitted.

How will the confidentiality of my data be protected?

This study will follow current legislation regarding data protection. The processing, communication and transfer of your data will be carried out in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on Data Protection (RGPD) and Organic Law 3/2018. , of December 5, on Protection of Personal Data and guarantee of digital rights.

At any time, you can access, correct or cancel your data. You can limit the processing of data that is incorrect, request a copy or have the data that you have provided for the study transferred to a third party (portability). To exercise your rights, contact the principal investigator of the study or the Data Protection Delegate of the Spanish Foundation of Endocrinology and Nutrition. We remind you that data cannot be deleted, even if you stop participating in the study, to ensure the validity of the research and comply with legal duties. You also have the right to contact the Data Protection Agency if you are not satisfied.

• Both the Center and the Promoter are respectively responsible for the processing of your data and undertake to comply with the data protection regulations in force. The data collected for the study will be identified by a code, so that no information that could identify you is included, and only your study doctor/collaborators will be able to relate data to you and your medical history. Therefore, your identity will not be revealed to any other person except the health authorities, when required or in cases of medical emergency. The Research Ethics Committees, the representatives of the Health Authority in matters of inspection and the personnel authorized by the Sponsor, will only be able to access to verify the personal data, the procedures of the clinical study and compliance with the standards of good clinical practice (always maintaining the confidentiality of information).

• The Researcher and the Promoter are obliged to retain the data collected for the study for at least 5 years after its completion. Subsequently, your personal information will only be retained by the health care center and by the promoter for other scientific research purposes if you have given your consent to do so and if permitted by applicable law and ethical requirements.

• If we transfer your encrypted data outside the EU to our group entities, service providers or scientific researchers who collaborate with us, the participant's data will be protected with safeguards such as contracts or other mechanisms by the protection authorities. of data. If the participant wants to know more about it, they can contact the Data Protection Officer of the promoter [protección.datos@seen.es].

Are there financial interests in this study?

This research is promoted by the Spanish Foundation of Endocrinology and Nutrition (FSEEN) and financed by FSEEN itself and the company Hologic, which makes the densitometer available to researchers. This company did not participate in the design of this study.

Physicians participating as researchers will not receive financial compensation for conducting this study.

Who can give me more information?

If you have any questions, you can consult with the professional who gave you this information. This will clarify any questions you may have about this study.

The main researcher at your center is Dr Vilarrasa Telephone: 932602784

INFORMED CONSENT

I, ...

(write your first and last name on this line and below, under Signature of Participant),

- I have had sufficient time to read this information carefully and make a decision about my participation.

- I have understood the content of the study and all my doubts were discussed and clarified.

- I understand that my participation is voluntary.

- I understand that I can withdraw from the project whenever I want, without having to give explanations and without this affecting my medical care.

- I freely give my consent to participate in the project and give my consent for my personal data to be processed under the conditions detailed in the information sheet, with the purpose of carrying out the project research and obtaining the results derived from the research.

- I am aware that I may exercise my right of access, rectification, opposition or cancellation at any time.

Signature of participant Name: .....

Date:

To be completed by the doctor or health professional

I have informed M/Mrs. .....

to the best of my ability so that I believe he/she has been able to understand the terms of participation in the SARCOBAR scientific study

Signature of doctor or healthcare professional

.....

Date

Copy to give to the patient

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Date

Copy to save in the study file