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Severe obesity and low muscle mass and function

Submission date
05/05/2024

Recruitment status
Recruiting

Registration date
19/06/2024

Overall study status
Completed

Last Edited
19/06/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Adiposity has a deleterious effect on the muscle since its infiltration by fatty tissue can alter its function. Emerging evidence indicates that both low muscle mass and decreased muscle quality have a strong negative prognostic impact, especially in people with obesity, and can lead to frailty, disability and increased morbidity and mortality. The term "sarcopenic obesity" (SO) has been proposed to identify this clinical situation in which obesity is combined with low skeletal muscle mass and function significantly increasing the deleterious effects that obesity exerts on health. However, the lack of a consensus definition has meant that studies to date have not allowed us to know the true consequences of this entity and most studies have been carried out in a population with non-severe obesity. Therefore, there has been low representation of people with the most significant degree of obesity (BMI>35kg/m2). In this clinical context, bariatric surgery is currently the most effective treatment to obtain significant weight loss that is sustained over time. A relevant concern is that after bariatric surgery there is loss not only of fatty tissue but also of muscle mass after surgery, which could add morbidity. For all these reasons, the detection of sarcopenia before surgery is of high importance to be able to closely monitor affected patients due to the risk of worsening after surgery. Moreover, the differential impact of each technique on body composition is still unknown. This study aims to estimate the prevalence of SO in people with severe obesity seen in Endocrinology and Nutrition outpatient clinics and create a Spanish multicenter registry. It will also analyze the impact of sarcopenia on health and quality of life and the effect of different types of bariatric surgery techniques on sarcopenia development.

Who can participate?
Patents aged 18-65 years old with severe obesity

What does the study involve?
The study involves an assessment of body composition and muscular strength, biochemical analyses and quality of life tests.

What are the possible benefits and risks of participating?
Participants will benefit from a closer follow-up by the research team. No health risks will be associated with the participation in the study.

Where is the study run from?
Spanish Society of Endocrinology and Nutrition Foundation (FSEEN)

When is the study starting and how long is it expected to run for?
September 2023 to January 2025

Who is funding the study?
Spanish Society of Endocrinology and Nutrition Foundation (FSEEN)

Who is the main contact?
Dr Nuria Vilarrasa, nuriag@bellvitgehospital.cat, nuriavilarrasa@yahoo.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
Nil known

Study information

Scientific Title
Spanish National Registry of sarcopenic obesity in patients with severe obesity

Acronym
SARCOBAR

Study objectives
Sarcopenic obesity is a prevalent entity among people with severe obesity followed in Endocrinology and Nutrition outpatient clinics and is associated with greater comorbidities and worse quality of life. Patients with severe obesity undergoing bariatric surgery will experience worsening of their muscle mass and function after the intervention, leading to an increase in the prevalence of sarcopenia. The loss in muscle mass will be higher in patients undergoing hypo-absorptive techniques and will be associated with a lower quality of life after surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/11/2023, Bellvitge University Hospital Ethics Committee (Feixa Llarga s/n, L´Hospitalet de Llobregat (Barcelona), 08907, Spain; +34 932607500; presidenciaceic@bellvitgehospital.cat), ref: PR243/23

Study design
Multicenter prospective observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Study of sarcopenia prevalence in patients with severe obesity

Interventions
Patients will be selected from the Endocrinology and Nutrition outpatient clinics of eight tertiary public reference hospitals in Spain for Obesity treatment. Once selected and after

signing the informed consent, clinical, anthropometric data, body composition, muscle functional assessment, analytical determination, quality of life and physical activity tests will be performed.

In the subgroup of patients undergoing bariatric surgery, a new control will be carried out one year after surgery with the study of body composition, muscle functional assessment, biochemical parameters, quality of life and physical activity tests.

Clinical variables to collect:
General data
o Age, sex
o Cardiovascular risk factors: diabetes mellitus, high blood pressure, dyslipidemia, smoking.
o Other comorbidities associated with obesity: obstructive sleep apnea syndrome, osteoarthritis, metabolic liver disease.

Body composition study:
o Anthropometry: Weight, height, body mass index, waist circumference, calf circumference.
o DXA (Hologic Horizon Wi®): Bone mass, fat mass (MG), fat-free mass (FLM), appendicular mass (ALM), Estimation of visceral fat.

ALM/weight, MG/weight, MLG/size2

Functional assessment:
o Hand dynamometry: Grip strength will be calculated using a Jamar-type dynamometer with the patient sitting, the elbow close to the trunk and flexed at a right angle, the carpus in a neutral position and the dynamometer on a support. The average of three measurements of each hand (dominant hand) will be collected.
- Assessment of biochemical parameters (laboratory of each center): glycemia, insulinemia, HOMA, HbA1c, kidney function (creatinine, glomerular filtration rate) and liver function (GOT, GPT, GGT), urate, lipid profile (total cholesterol, HDL cholesterol, cholesterol LDL, triglycerides) bone metabolism parameters (calcium, phosphorus, magnesium, PTH, 25OH vitamin D, osteocalcin, beta cross laps), albumin, prealbumin and retinol binding protein and C-reactive protein.
- In the subgroup of patients undergoing bariatric surgery, a determination of myokines (myostatin, apelin, irisin) and inflammatory cytokines (TNF receptor 1 and 2, IL-6) will be performed.
- Medical treatments used: pharmacological treatment for T2DM (metformin, insulin, iSGLT2, GLP-1 receptor analogues) hypotensive agents, lipid-lowering agents
- Quality of life test: IWQOL-Lite
- The Rapid Assessment of Physical Activity (RAPA) questionnaire
- Date and type of bariatric surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Prevalence of sarcopenic obesity in people with severe obesity followed in Endocrinology and Nutrition outpatient clinics in reference centers for obesity treatment in Spain measured using patient records at the end of the study

Key secondary outcome(s))

1. Muscle strength measured using hand dynamometry 12 months after surgery
2. Appendicular lean mass measured using bone density test (DXA) evaluation at baseline and 12 months after surgery
3. Muscle function measured using plasma myokine determinations at baseline and 12 months after surgery
4. Prevalence of T2DM (in percentage) defined as HbA1c ≥ 6.5% or fasting glucose in two occasions >7 mmol/l or use of antidiabetic treatment measured using plasma analysis at baseline and 12 months after surgery
5. Prevalence of hypertension (in percentage) defined as systolic and diastolic blood pressure ≥ 140/90 or treatment with antihypertensive drugs measured using sphygmomanometer at baseline and 12 months after surgery
6. Prevalence of dyslipidemia defined as total cholesterol >200 mmol/l, LDL cholesterol >130 mmol/l or treatment with lipid-lowering treatment measured using plasma analysis at baseline and 12 months after surgery
7. Prevalence of obstructive sleep apnea defined as apnea-hypopnea index ≥ 5 events/hour with OSA symptoms or ≥ 15 events/hour without OSA symptoms measured using polysomnography at baseline and 12 months after surgery
8. Quality of life measured using the IWQOL-Lite test at baseline and 12 months after surgery
9. Physical activity performance measured using the Rapid Assessment of Physical Activity (RAPA) questionnaire at baseline and 12 months after surgery
10. Glucose control using HbA1c [measured using plasma analysis] at baseline and 12 months after surgery
11. Insulin resistance using HOMA measurements at baseline and 12 months after surgery
12. Lipid profile using total and LDL cholesterol measurements in the laboratory at baseline and 12 months after surgery
13. Sarcopenia prevalence (in percentage) according to surgical treatments (Sleeve gastrectomy, gastric bypass, duodenal switch/SADI-S) measured using data collected from DXA evaluation 12 months after surgery
14. Surgical complications measured using the Clavien-Dindo classification of surgical complications measured using data collected from medical records within 90 days of surgery
15. Percentage of comorbidities remission (T2DM, Hypertension, Dyslipidemia) measured using measured data collected from medical records 12 months after bariatric surgery

Completion date
12/01/2025

Eligibility

Key inclusion criteria
1. Men and women aged between 18 and 65 years
2. Diagnosis of obesity with a body mass index greater than or equal to 35 kg/m2 with associated comorbidities or BMI >40 kg/m2
3. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Weight greater than 227kg (load capacity limit DXA Hologic-Horizon WI model)
2. End-stage renal disease
3. Liver cirrhosis more advanced than Child A
4. Congestive heart failure NYHA grade 3-4
5. Serious limitations of functional capacity that prevent moving to the vehicle with the densitometer
6. Pregnancy
7. History of previous bariatric surgery
8. Not capable of granting informed consent
9. Patient refusal to participate in the study

Date of first enrolment
01/06/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
Spain

Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Sociedad Española de Endocrinología y Nutrición

ROR
https://ror.org/01tk4y529

Funder(s)

Funder type
Research organisation

Funder Name
Fundación SEEN

Alternative Name(s)
Society of Endocrinology and Nutrition Foundation, Foundation of the Spanish Society of Endocrinology and Nutrition, FSEEN

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the study will be available upon request from Dr Nuria Vilarrasa, nuriag@bellvitgehospital.cat.

All individual participant data collected during the trial will be shared upon request, after identification and publication, including the study protocol, statistical analysis plan, informed consent form, clinical study report, and analytic code. Informed consent of patients will be

obtained to enter the study and to share data. In the database the patient will be identified by a numerical code, without name or surname. Access to personal information will be restricted to the study doctor/collaborators, Research Ethics Committee and personnel authorized by the promoter, when necessary to verify the data and procedures of the study, but always maintaining their confidentiality in accordance with the current legislation.

All data collected in this study will be confidential and will be treated in accordance with Regulation (EU) 2016/679, General Data Protection and the Organic Law on Data Protection and Guarantee of Digital Rights (LOPDGDD) that entered into force on December 6, 2018 and whose objective is to adapt Spanish legislation to European regulations, defined by the General Data Protection Regulation (RGPD), in force since May 25, 2018 and Law 14/2007, July 3, Biomedical Research.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			28/05/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes