Evaluation of different methods to measure muscle mass and strength in a population with class II/III obesity: A Follow-up Study

Published: 09-03-2023
Last updated: 21-12-2024

Primary objective: To assess the validity of US to measure lean mass after weight loss in a population of bariatric surgery patients.Secondary Objectives: • To assess de differences in lean mass between DXA and US in this study compared to the...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53356

Source
ToetsingOnline

Brief title
MUSCLE-II study

Condition

- Other condition

Synonym
Obesity, Overweight

Health condition

morbide obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Wetenschapsstichting CON

Intervention

Keyword: Muscle, Obesity, Ultrasonography

Outcome measures

Primary outcome

The main parameters of this study are: lean mass measured by DXA and US. The main endpoint of this study is the validity of the US measurement of lean mass compared to DXA.

Secondary outcome

The secondary parameters include: weight loss after surgery, lean mass change after surgery and comorbidities (baseline vs. 1 year after surgery), results of blood tests.

Other study parameters are some patient characteristics:

- Demographics: sex, age and ethnicity.

- Clinical data from the first year follow-up appointment: anthropometric measures, medical history, underlying diseases, medication use, results of blood tests, food-record and questionnaire.

Study description

Background summary

Weight loss therapies should aim to reduce fat mass while preserving both muscle mass and muscle strength. Consequently, there is a need for validated methods to measure muscle mass and strength. Current methods are either expensive and require trained technicians, or have not been validated in populations with class II/III obesity (BMI > 35 kg/m2). In our previous studies (MUST-MOP and MUSCLE study), we have validated the use of ultrasound (US) for the measurement of lean mass (a proxy for muscle mass) in a population with obesity. These studies showed that the use of US for the measurement of lean mass was feasible, reliable and valid. The aim of the current study is to validate the use of US for the measurement of lean mass after weight loss in a population of bariatric surgery patients.

Study objective

Primary objective: To assess the validity of US to measure lean mass after weight loss in a population of bariatric surgery patients.

Secondary Objectives:
• To assess de differences in lean mass between DXA and US in this study compared to the MUSCLE-study.
• To assess how the lean mass has changed after bariatric surgery and the effects of lean mass on total weight loss and resolution of comorbidities
• To assess whether the change in lean mass has an effect on serum levels of markers for muscle mass.

Study design

This study is an observational follow-up study of the MUSCLE study and will take place in the Centre Obesity Northern-Netherlands (CON) at the Medical Centre Leeuwarden (MCL).

Study burden and risks

There are no direct benefits for the participants. However, the results of this study can help to further validate the ultrasound as a cheaper and more accessible method to measure muscle mass. This can potentially be used in standard clinical care to assess muscle mass of patients during weight loss.
• The additional time investment: during first year follow-up appointment approximately 30 minutes.
The risks of most test are minor, even the small amount of radiation exposure, which means the risks and burden of this study outweigh the potentially obtainable knowledge.

Contacts

Public
Medisch Centrum Leeuwarden

Henri Dunantweg 2
Leeuwarden 8934 AD
NL
Scientific
Medisch Centrum Leeuwarden

Henri Dunantweg 2
Leeuwarden 8934 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Participation in MUSCLE-study

Exclusion criteria

(1) Weight over 204 kg; (2) pregnancy; (3) pacemaker.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-06-2023
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-03-2023
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83747.099.23