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

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Primary Objective: To assess which method for measuring muscle mass is most reliable compared to dual-energy X-ray absorptiometry (DEXA) scan in a population with class II/III obesity.Secondary Objectives:1. To assess which combination of methods…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON54850

Source
ToetsingOnline

Brief title
MUSCLE-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: Ministerie van OC&W

Intervention

Keyword: Evaluation, Measurement, Muscle, Obesity

Outcome measures

Primary outcome

Main parameters: muscle mass measured by DEXA, ultrasound (US), bioelectrical impedance analysis (BIA), anthropometric methods and 24-hour urine creatinine.

Main endpoint: correlation between muscle mass measured by DEXA and one of the parameters.

Secondary outcome

Secondary parameters: muscle strength measured by handgrip strength; biochemical measures; protein intake; and physical activity measured with movement sensors and short questionnaire to assess health-enhancing physical activity (SQUASH).

Secondary endpoint: the correlation between multiple parameters for muscle mass and muscle strength and the muscle mass measured by DEXA.

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: 35-45 kg/m2). Therefore, the aim of this study is to validate other methods or a combination of methods to measure muscle mass in a population with class II/III obesity.

Study objective

Primary Objective: To assess which method for measuring muscle mass is most reliable compared to dual-energy X-ray absorptiometry (DEXA) scan in a population with class II/III obesity.
Secondary Objectives:
1. To assess which combination of methods for measuring muscle mass and muscle strength is most reliable compared to the DEXA scan in a population with class II/III obesity.
2. To assess the variance in muscle mass measured by DEXA in a population with class II/III obesity.
3. To assess the influence of nutrition, exercise and hormones on muscle mass.

Study design

This study is a prospective cross-sectional study and will take place in the Center Obesity Northern Netherlands (CON) at the Medical Center Leeuwarden (MCL).

Study burden and risks

There are no direct benefits for the participants. However, the results of this study may help to find a cheaper and more accessible method of measuring muscle mass and strength in this population. This can be used to apply in standard clinical care, to assess muscle mass of patients during weight loss.
The burden associated with this study includes:
- Additional time investment: During first intake approximately 1 to 1.5 hours extra, at home there is an extra 5 minutes every time patients/volunteers need to urinate (for urine-collection) and approximately 10 minutes to fill in the SQUASH questionnaire.
- Physical activity: During the measurement of handgrip strength, the patients/volunteers might move differently or more than they are used to, which can result in minor muscle ache the days after measurement.
The risks of most test are minor, even the small amount of radiation exposure, and we think that the potentially obtainable knowledge outweighs the risks and burden of this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Between 18 and 65 years of age.
- BMI above 35 kg/m2

Exclusion criteria

- History of bariatric surgery
- Inability to perform physical tests
- Inability to communicate in either Dutch or English
- Weight over 204 kilograms (due to limitations of the DEXA)
- BMI above 50 kg/m2
- Pregnancy

- Pacemaker

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2020
Enrollment:	0
Type:	Actual

Medical products/devices used

Generic name:	Sonography
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-01-2020
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	15-02-2021
Application type:	Amendment
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

ID: 28423
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL71609.099.19
OMON	NL-OMON28423

Study results

Date completed:	24-06-2022
Actual enrolment:	84