Feasibility and reproducibility of different methods to define muscle mass in obese patients

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Primary Objective: to investigate feasibility and reproducibility of different methods to define muscle mass in obese patients. Secondary Objective(s): whether quality of life is linked to muscle mass and strength in obese individuals.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48024

Source
ToetsingOnline

Brief title
Different methods to define muscle mass in obese patients

Condition

- Other condition

Synonym
obesity, overweight

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Muscle mass, Obesity, Sarcopenia

Outcome measures

Primary outcome

The main study parameter is the reproducibility of different methods to define muscle mass in obese patients. We will look both at intra- and inter-observer variation.

Secondary outcome

We will also investigate correlation between quality of life and muscle mass and strength. Furthermore, the correlation between 24h urine creatinine and measurements of muscle mass and strength will also be studied.

Study description

Background summary

Obesity is a global health problem. Together with overweight, one third of the total world population is affected, with numbers expecting to rise further in the upcoming decades. Obesity increased the risk of comorbidities such as cardiovascular disease, type 2 diabetes mellitus, sleep apnoea, depression, and mortality. Obesity is also associated with negative effects on skeletal muscle. These include an increased risk developing functional disabilities, including postural, mobility, strength and dynamic balance limitations. Something which is often overlooked in obese patients is sarcopenic obesity. Sarcopenia is defined as low muscle mass and either low muscular strength or low physical performance. Different methods can be used to define muscle mass, where the golden standard technique are imaging techniques such as magnetic resonance imaging (MRI) and computed tomography (CT). The problem with these imaging methods are the weight and radial size limitations. Tools that can be used to

estimate muscle mass and strength indirectly are easy and less costly than the earlier mentioned methods. Examples of these calculations are limb circumference, skinfold thickness, bioelectrical impedance analysis, handgrip strength test, stair stand test, and a 6-minute walking test. Until now, these tests have not been validated in class II and III obese populations.

Study objective

Primary Objective: to investigate feasibility and reproducibility of different methods to define muscle mass in obese patients.
Secondary Objective(s): whether quality of life is linked to muscle mass and strength in obese individuals.

Study design

This study is cross-sectional without intervention. Measurements will take place on the day of screening of patients who have applied for bariatric surgery. The main procedures are anthropometric measurements, 6-minute walking test, hand grip strength test and chair stand test. Urine will be collected during a period of 24 hours for creatinine levels. Correlation with quality of life score and blood parameters , which are both already included in standard patient care will also be investigated.

Study burden and risks

Both the risks and the benefits are limited for the patients. The various measurements will take some extra time during the visit. There is also some physical and mental effort required for the patient, something which they might not be familiar with. This could result in minor muscle strain the days after. The results of this study could be helpful for future patients undergoing bariatric surgery.

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

Aged between the age of 18 and 65 years old.
BMI of at least 40kg/m2.
BMI of at least 35kg/m2 with comorbidities eligible for bariatric surgery

Exclusion criteria

Previous history of bariatric surgery.
Unable to perform physical tests.
Serious conditions precluding physical tests.
Unable to communicate in Dutch or English.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	16-04-2019
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	NL69293.099.19
Other	TBA