Feasibility and Reliability of the Muscle Sound® Technique in a Morbidly Obesity Population

Published: 27-05-2019
Last updated: 15-05-2024

Evaluation of the feasibility and reproducibility of Muscle Sound® in a morbid obese population.

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

Summary

ID

NL-OMON48158

Source
ToetsingOnline

Brief title
MUST-MOP

Condition

- Other condition

Synonym
Obesity Overweight

Health condition

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: Muscle, Obesity, Sonography

Outcome measures

Primary outcome

The main endpoint is the feasibility of Muscle Sound® by using the percentage

of successful measurement at 7 different sites of the body.

Secondary outcome

Reliability (intra- and inter-observer variance)

Study description

Background summary

In obesity, muscle mass is estimated to be relatively low. A low muscle mass together with high fat mass is also called sarcopenic obesity. Sarcopenic obesity has been associated higher risks of diabetes mellitus type 2 and hypertension, compared to general obesity. Sarcopenic obesity is also characterized by lower psychological health, quality of life and all-cause mortality compared to general obesity. This indicates that it is important to preserve muscle mass during weight loss, which leads to a need for validated methods for estimating muscle mass in obese populations. Recently new software to quantify muscle with ultrasonography has been developed (Muscle Sound®). This software has been validated in healthy adults, athletes and critically ill patients. However, this software has yet to be validated in an obese population.

Study objective

Evaluation of the feasibility and reproducibility of Muscle Sound® in a morbid obese population.

Study design

This study is a prospective observational study to look at the feasibility and reproducibility of ultrasonography to quantify muscle.

The patient will arrive at the MCL two hours prior to the bariatric surgery. The first two measurement will be performed by two different researcher, while the patient is waiting for the surgery. This is possible because the patient is expected to be at the hospital ward 2 hours prior to surgery.

The third and final measurement will take place the day after bariatric surgery. All patients receiving bariatric surgery will stay at the hospital ward for at least 1 night, which makes it possible to measure them the day after surgery.

The measurement itself will take approximately 5 minutes, and the patient will be asked to stand during the measurement.

Study burden and risks

Both the risks and benefits of this study will be minimal for the subjects. Sonography measures with sound waves, which do not cause damage to the underlying tissues. In patients, it can cause slight discomfort as various body parts will be measured.
Patients with known allergies for sonography gel are excluded from the study, however unknown allergy for sonography gel can possibly cause an allergic skin reaction. Skin reactions due to sonography gel are very rare (only mentioned in case reports), and are mostly related to allergic contact dermatitis or contact urticarial.

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

All patients scheduled for bariatric surgery at the Center for Obesity Netherlands (CON) are eligible to participate in this study.

Exclusion criteria

Allergy to one (or more) of the ingredients of the sonography gel

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):	25-06-2019
Enrollment:	50

Type:	Actual

Medical products/devices used

Generic name:	Sonography
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-05-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	04-07-2019
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: 24685
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69211.099.19
OMON	NL-OMON24685