Measuring muscle size and muscle quality in healthy adults: validity and reliability of ultrasound measurements using a curved-array transducer.

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This study aims to investigate the validity and reliability of US to measure muscle size and muscle quality in healthy adults compared to MRI/MRS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53158

Source
ToetsingOnline

Brief title
Validity and reliability of ultrasound muscle imaging

Condition

- Muscle disorders

Synonym
muscle weakness, Sarcopenia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Muscles, Reliability, Ultrasound, Validity

Outcome measures

Primary outcome

Agreement between US and MRI/MRS in the area of muscle size (expressed in

rectus femoris cross-sectional area) and rectus femoris quality.

Secondary outcome

Agreement between US (curved array transducer) and US (linear array transducer)

in the area of muscle size (expressed in rectus femoris cross-sectional area).

Study description

Background summary

Sarcopenia, defined as a progressive loss of muscle mass and function, is a result of the process of aging and is associated with functional decline and disability. As poor function of especially thigh muscles is associated with loss of mobility, the assessment of thigh muscles has become an important clinical measure for older adults. Currently, Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) are considered to be the *gold standard* for the assessment of thigh muscle size and muscle quality. However, high costs, long scanning times and accessibility are major drawbacks of these techniques. Because of its non-ionizing nature ultrasound (US) has been suggested to assess muscle size and muscle quality, but complete understanding about validity and reliability of ultrasound is lacking.

Study objective

This study aims to investigate the validity and reliability of US to measure muscle size and muscle quality in healthy adults compared to MRI/MRS.

Study design

To assess validity of US, the participants will be measured with MRI and US once during a single day. To assess reliability of US, a second US scan will be performed with a one-week interval.

Study burden and risks

During the study participants will undergo one MRI/MRS and two US scans. Furthermore, body weight and length will be assessed. The US scans and the MRI/MRS scan pose no health risks and are proven not to be stressful for the individual. The most reported side effect of MRI scan is slightly warming of the body, however this is not considered to be harmful. No side effects of US scans are known. This study is not expected to cause any additional physical harm to the subjects* health. Therefore, we consider the burden of these study measurements to be minimal (about 60 minutes at the first assessment and 30 minutes at the second assessment) and the risk negligible. Participants can withdraw from the study at any time; this has no consequences for the participant.

Contacts

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Eligibility criteria

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

Inclusion criteria

-Adults aged between 18 and 65 years old.
-Able to understand and speak the Dutch language

Exclusion criteria

-Participants who have a heart pacemaker or implants
-Participants with severe claustrophobia
-Participants who have severe neuromuscular diseases or functional impairments
- Written informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2017
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO

Date:	11-12-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	10-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL51462.042.14