The Muscle Quality Index: linking quantitative MRI to muscle function

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In this exploratory study we aim:1) To identify the confounding factors in qMRI analysis (e.g. age, gender, body composition)2) To determine the relation between qMRI parameters and muscle force and function taking into account the confounding...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON56280

Source
ToetsingOnline

Brief title
Motion

Condition

- Muscle disorders

Synonym
concerns study in healthy volunteers, N/A

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: VIDI

Intervention

Keyword: MRI, Muscle, Muscle function

Outcome measures

Primary outcome

The primary outcome measures are isometric and isokinetic muscle force and the obtained qMRI parameters:

- Muscle fat fraction, muscle volume, muscle length, and muscle shape assessed with a Dixon sequence.

- T2 relaxation time of muscle water (T2water) assessed with a multi-slice multi spin echo sequence.

- Mean diffusivity, fractional anisotropy, estimated muscle fibre length, muscle pennation angle and physiological cross-sectional area assessed with a diffusion weighted sequence.

Other study parameters are the potential confounders in qMRI, like age, body weight, height, and composition, daily-life activity levels, and smoking and drinking history.

Secondary outcome

n.a.

Study description

Background summary

Neuromuscular diseases are characterized by progressive muscle wasting, leading to disability, significant reduction of quality of life, or even death.
Magnetic resonance imaging (MRI) allows non-invasive, quantitative evaluation of muscle architecture, status, and microstructure in those patients. However,

although sensitive, quantitative MRI (qMRI) parameters often lack specificity and are not linked to muscle function. Furthermore, the within-group variance in qMRI parameters is large, which requires large sample sizes in clinical trials. This is a problem in rare diseases, like neuromuscular disorders. Identifying the confounding factors that lead to this within-group variance and accounting for these factors in qMRI muscle analysis will reduce the needed samples size and will allow better patient-specific evaluation of disease progression and effect of therapy.

Study objective

In this exploratory study we aim:
1) To identify the confounding factors in qMRI analysis (e.g. age, gender, body composition)
2) To determine the relation between qMRI parameters and muscle force and function taking into account the confounding factors determined in aim 1.

Study design

This is an observational cohort study. Study assessments include an MRI scan and muscle strength measurements of the lower extremity, a body composition measurement with bioimpedance, and questionnaires on daily-life activity and life-style.

Study burden and risks

The participants will undergo one 60 minute MRI scan. This involves risks regarding to claustrophobia and back pain due to laying in supine position. Furthermore, the participants needs to perform muscle strength measures, which can lead to muscle soreness the day after. There will be no direct benefit for the participants themselves. The work will allow us to better study muscle changes in patients who suffer from diseases affecting muscles, and will be of interest for the evaluation of injuries and recovery in athletes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

• Age between 16 and 60 years old
• BMI between 18 and 30 kg/m2

Exclusion criteria

• History of neuromuscular disease
• Contra-indications for undergoing an MRI scan (e.g. because of pacemaker, claustrophobia, metal implants, metal splinters in the eye)
• Inability to lie supine for 60 minutes
• Inability to perform knee extension or knee flexion
• Contra-indications for physical exercise without prior consultation with a physician verified using the Physical Activity Readiness Questionnaire (PAR-Q).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-02-2023
Enrollment:	162
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	18-01-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	05-12-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL82307.041.22