Innovation of MR based assessment of muscle function during in-magnet exercise

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to determine the feasibility, repeatability and sensitivity of our newly developed non-invasive dynamic MR acquisitions to study muscle contractile function and muscle oxidative capacity during dynamic exercise. Muscle oxidative capacity will be...

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

Summary

ID

NL-OMON53413

Source
ToetsingOnline

Brief title
Novel Dynamic MRI acquisitions to study muscle function

Condition

- Muscle disorders

Synonym
Muscle disorders; Ageing

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: NWO

Intervention

Keyword: dynamic MRI, muscle function, sarcopenia, Skeletal Muscle

Outcome measures

Primary outcome

For the muscle oxidative capacity the main endpoints are the repeatability of/ and sensitivity to changes in high-energy phosphate metabolites, including adenosine triphosphate (ATP), phosphocreatine (PCr), inorganic phosphate (Pi), myofiber pH and T2* relaxation times measured at rest, during a supine cycling test and during recovery. The main endpoints for the assessment of muscle contractile function are the feasibility of/ repeatability of/ and sensitivity to changes of the strain rate and strain rate distributions along and perpendicular to the fibers measured during knee-flexion & -extension exercise.

Secondary outcome

Secondary study parameters:

• Muscle Morphology measures using qMRI (Muscle volumes; Fat fractions; architectural parameters, diffusion measures; water T2 relaxation times)
• Hand grip strength
• Motor function tests (e.g. KATZ score, SPPB, IADL, TUG)
• BMI (height & weight)
• Blood pressure
• 7-day Activity levels
• Questionnaires (e.g. fall history, co-morbidities(CIRS), mental functioning

(MOCA), daily life activities (IPAQ), feasibility of the in-magnet exercises)

Study description

Background summary

Sarcopenia is a recently-classified disease that is characterized by the progressive loss of skeletal muscle mass and function, which typically occurs from middle-age onwards. Its increasing prevalence is becoming a major societal problem, given its associations with frailty, falls, fractures, and hospitalization. The etiology of impaired muscle function with increasing age is multifactorial, with both muscle strength and muscle oxidative capacity being important contributors. However, the currently available techniques to measure underlying factors influencing muscle function are invasive or lack specificity with respect to contribution of individual muscle. More insight in the underlying factors contributing to impaired muscle function with increasing age, will help to further optimize exercise, dietary and/or pharmacological interventions.

Study objective

to determine the feasibility, repeatability and sensitivity of our newly developed non-invasive dynamic MR acquisitions to study muscle contractile function and muscle oxidative capacity during dynamic exercise. Muscle oxidative capacity will be measured during a supine cycling test using interleaved T2* mapping and phosphorous magnetic resonance spectroscopy (31P MRS) acquisitions. Muscle contractile function will be measured using time-resolved 3D phase contrast acquisitions during a knee flexion and extension test.

Study design

2-way prospective observational feasibility and repeatability study

Study burden and risks

Participants will be asked to visit the hospital one or two times. During these visits a static and dynamic MRI acquisition are performed in rest and during in-magnet exercise. A selection of the participants will also be asked to perform some functional tests, fill-out questionnaires and collect wearable data for a period of 7-days. There are no medical risks associated with this study. The MRI scan is safe and painless. An MRI scan does not cause radiation and no drugs will be administered. The scanner does make a lot of noise, so we will give you hearing protection to reduce the noise. Some people find lying in

the MRI scanner uncomfortable. The exercise test done during the second part of the MRI scan may cause some muscle fatigue. A hospital staff member will be constantly present and in touch while you are in the scanner, and if you are uncomfortable the scanning can be stopped. There are no known risks associated with answering the questionnaires or performing the functional tests. After performing the functional tests, the muscles may feel a little tired. There is a significant time investment on behalf of the participants, since participants are required to visit the institute on one or two occasions. The visits range in duration from 1.5 to 4.5 hours per session. Participants will receive personal feedback of their results, this will not directly lead to better health care or health care advice. Participants will receive reimbursement for their travel and parking costs. Participants have no direct benefit by participating in this study. A group-related benefit of this observational study is that in the future dynamic MR acquisitions might become a valuable tool in research and management of impaired muscle function in ageing, sarcopenia, muscle disease and mapping the recovery of muscle injuries.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with sarcopenia.
In order to be eligible to participate in this study, a participant must meet the following criteria:
• Non-hospitalized individuals
• Ability to follow test instructions
• Age above 65 years
• Diagnosed with Sarcopenia according to the SARC-F questionnaire and handgrip Strength

Patients with neuromuscular diseases
In order to be eligible to participate in this study, a patient must meet the following criteria:
• Confirmed NMD diagnosis
• Referral to supervised exercise rehabilitation program
• Ability to follow test instructions
• Non-hospitalized individuals
• Age > 18 years

Athletes with hamstring injury
In order to be eligible to participate in this study, an athlete must meet the following criteria:
• Anamnestic pain in posterior thigh
• Localised pain during palpation of hamstring muscle
• Localised pain during passive straight leg raising
• Increasing pain during isometric contraction
• Age> 18 years old

Control participants
In order to be eligible to participate in this study, a participant must meet the following criteria:
• Non-hospitalized individuals
• Ability to follow test instructions
• Age> 18 years

Exclusion criteria

• Inability to provide informed consent

• Have a history of claustrophobia
• Patients/ participant is not eligible to perform the exercise test described in this study protocol or follow instructions
• Contra-indication for MRI (e.g., pacemaker, Claustrophobia; See F1 vragenlijsten screening MRI Amsterdam UMC)
• Muscle injury in the 6 months prior to participation in this study (Except for the athletes)
• Being under investigation for non-diagnosed disease at the time of investigation
• Risk factors for exercise testing registered by a Dutch version of the pre-participation questionnaire (American college of sports medicine and American Heart association). Possible risk factors will be discussed with a medical specialist or general practitioner before a subject can be included.

Specific exclusion criteria for adults with Neuromuscular disease
• Engaged in an exercise program for a period longer than 4 weeks in the past 6 months.
• Participants with variably of rapidly progressive NMD, characterized by muscle impairment that worsens over months, e.g. amyotrophic lateral sclerosis.
• Participants who are not stable on medication.
• Participants with cardio-pulmonary involvement.

Specific exclusion criteria for Athletes with hamstring injury:
• Cause of the hamstring injury is an extrinsic trauma of the posterior thigh
• Patient does not have the intention to return to full sports activity

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2023
Enrollment:	178
Type:	Anticipated

Medical products/devices used

Generic name:	MRI spftware patch
Registration:	No

Ethics review

Approved WMO Date:	06-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL82616.018.22