Some control values for MR biomarkers of fatty infiltration and edema-like lesions in skeletal muscles of healthy volunteers - an explorative study

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To obtain some control values for the MRI biomarkers for fatty infiltration and edema-like lesions in skeletal muscles of healthy volunteers.

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

Summary

ID

NL-OMON43552

Source ToetsingOnline

Brief title Skeletal muscle MR in healthy volunteers

Condition

Muscle disorders

Synonym muscle disease, Steinert Disease

Research involving Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum **Source(s) of monetary or material Support:** EU Seventh Framework Programme

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(#305697) on DM1 (OPTIMISTIC)

Intervention

Keyword: MRI, muscular dystrophy, myotonic dystrophy type 1, skeletal muscle

Outcome measures

Primary outcome

The two main study parameters are the fat fraction and T2 relaxation time of

all muscles in both the upper and the lower leg.

Secondary outcome

NA

Study description

Background summary

Patients with muscular dystrophy are characterized by progressive skeletal muscle degeneration, edema-like lesions and replacement of muscle tissue by fat. Together, this leads to progressive loss in muscle strength. In various types of muscular dystrophy (e.g. facioscapulohumeral dystrophy (FSHD) and Duchenne muscular dystrophy) it has been found that Magnetic Resonance Imaging (MRI) can be very useful in the understanding of the disease as well as for evaluation of treatments. Currently, a skeletal muscle MRI study is being performed in patients with the muscular dystrophy disease Myotonic Dystrophy type 1 (DM1). This skeletal muscle MRI study is performed within the multicenter trial OPTIMISTIC where the effect of cognitive behavioural therapy in patients with DM1 is investigated (NL nr: 46914.091.13). The two goals of the skeletal muscle MRI study are to evaluate MRI biomarkers of fatty infiltration and edema-like lesions 1) to get more insight in the disease process and 2) to evaluate the possible effects of the cognitive behavioural therapy. To be able to achieve these goals, it is important to investigate some control values for these MRI biomarkers of fatty infiltration and edema-like lesions. It is known that values of MRI biomarkers depend on the MRI scanner and the scanning protocol, so they cannot be easily obtained from the literature. Hence, to evaluate whether our findings in DM1 patients indeed deviate from healthy people, we would like to obtain some control values by scanning healthy volunteers.

Study objective

To obtain some control values for the MRI biomarkers for fatty infiltration and edema-like lesions in skeletal muscles of healthy volunteers.

Study design

Observational cross-sectional study whereby the volunteers undergo an MRI scan the legs.

Study burden and risks

The proposed study is fully non-invasive and the added risk according to the NFU document *Kwaliteitsborging mensgebonden onderzoek 2.0* is rated as negligible. Therefore, the burden for the volunteers is relatively small. The maximum duration of the MR experiment is 1 hour, which can be easily tolerated by healthy subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

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Eligibility criteria

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

Inclusion criteria

Healthy; MR eligibility

Exclusion criteria

MR ineligible; inability to lie supine for 60 minute

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):	20-04-2016
Enrollment:	10
Туре:	Actual

Ethics review

Approved WMO	
Date:	19-04-2016
Application type:	First submission

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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 CCMO **ID** NL55998.091.16