Muscle ultrasound: A potential new tool to diagnose and evaluate treatment in dermatomyositis and polymyositis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22461

Source
NTR

Brief title
Muscle ultrasonography in dermatomyositis and polymyositis

Health condition

Myositis, polymyositis, dermatomyositis, muscle ultrasound, corticosteroid induced myopathy

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
Source(s) of monetary or material Support: Dutch Arthritis Association (Reumafonds)

Intervention

Outcome measures

Primary outcome

1. Diagnostic value muscle ultrasound: Sensitivity, specificity en predictive value;

2. Monitoring disease activitiy muscle ultrasound: Correlation between muscle ultrasound and

muscle strength/function (MRC and dynamometry), patient reported outcome (HAQ, SF-36, VAS patient and patient reported outcome questionnaire), Myositis Disease Activity Assessment Tool (MDAAT) and Myositis Damage index (MDI);

3. Corticosteroid myopathy: Structural muscle muscle changes defined by ultasound in patients with chronic corticosteroid use.

Secondary outcome

N/A

Study description

Background summary

Background:

Optimal and quick diagnosis of idiopathic inflammatory myopathies such as dermatomyositis (DM) and polymyositis (PM) is important as these are treatable conditions. At this moment treatment effect is mainly based on clinical evaluation and functional scores, whereas other investigations (electromyography (EMG) and muscle biopsy) are difficult to repeat, because of its invasiveness. New diagnostic and objective instruments to aid in the diagnosis and monitoring treatment are therefore necessary. Ultrasound imaging (US) is easily applicable and proves to be useful in detecting various neuromuscular disorders. Muscle US might be of additional value in diagnosing DM and PM and might also aid in evaluating treatment response.

Objectives:

The aim of this study is to assess the diagnostic and monitoring properties of muscle US and to investigate if US is able to distinguish a myositis flare-up from a steroid-induced myopathy.

Method:

Patients suspected for the diagnosis will be invited to take part in the study. Additional to standard care muscle US and MRI will be performed. Furthermore, muscle force will be assessed by dynamometry and muscle function test (FI-2).

Newly diagnosed patients and patients that have been diagnosed will be requested to participate in the assessment of monitoring properties of US. Patients will be followed for one

year in which muscle US, Health Assessment Questionnaire (HAQ), dynamometry and FI-2 will be assessed at a 3 month interval. In addition MRI, EMG and muscle biopsy will be performed at the end of this follow-up year.

Patients that have been diagnosed and newly diagnosed patients will also be invited to participate in a prospective follow-up during the full length of the study to monitor a possible myositis flare-up. In case of possible myositis flare-up US will be repeated. Patients with a steroid-induced myopathy will be selected from the department of Hematology and Gastroenterology to serve as controls.

Results:

Data from this study will elucidate the diagnostic and monitoring properties of muscle US. Furthermore, the capability of muscle US to differentiate between myositis flare-up and steroid-induced myopathy will be determined. Based on this information diagnostic and monitoring strategy can be developed, where effectiveness, cost effectiveness and time efficiency will be optimized. Ultimately this will lead to patient care, where invasive procedures are minimized and optimal treatment can be achieved.

Study objective

1. Muscle ultrasound is capable to detect dermatomyositis and polymyositis in suspected patients;

2. Muscle ultrasound is capable to detect improvement of structural muscle changes induced by treatment;

3. Muscle ultrasound is capable to detect corticosteroid induced myopathy.

Study design

Patients are followed for one year at regular three, six or twelve monthly visits.

Intervention

Each measurment conducted for this study consist of 3 parts: Muscle ultrasound assessment, questionnaires and muscle function/strength assessment.

In addittion newly diagnosed patients and patients with a flare-up are asked to undergo a muscle biopsy, electromyography and muscle MRI at the end of follow-up (12 months).

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Eligibility criteria

Inclusion criteria

1. Patients suspected of dermatomyositis or polymyositis based on: Myalgia, muscle weakness, typical skin lesion and/or elavation of serum CK;

2. Dermatomyositis and polymyositis patients diagnosed according to the Bohan and Peter criteria;

3. Patients suspected of a corticosteroid induced myopathy.

Exclusion criteria

1. Patients on immunosuppressive medications > 2 weeks;

2. Patients younger than 18 years of age.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-03-2011
Enrollment:	154
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-02-2011
Application type:	First submission

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
NTR-new	NL2655
NTR-old	NTR2783
Other	CMO regio Arnhem-Nijmegen : 2010/469
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A