Optimization of diAgnostic accuracy in iDiopathic inflammAtory myopathies

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We hypothesize that an evidence based diagnostic algorithm, using fewer and preferably the least invasive diagnostic modalities can approach the accuracy of the complete panel of diagnostic tests.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20832

Source
NTR

Brief title
ADAPT

Health condition

Patients suspected of myositis

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

To compare the diagnostic accuracy and patient burden of testing strategies in patients

suspected for idiopathic inflammatory myopathy who qualify for treatment with corticosteroids. Diagnostic accuracy will be based reference diagnosis of an expert panel.

Secondary outcome

Cost-effectiveness analysis

Study description

Background summary

Idiopathic inflammatory myopathies (IIM) are a heterogeneous group of immune related diseases, that need to be treated with prednisone (with the exception of IBM). Because of heterogeneity, patients present with a range of clinical features, and a timely diagnosis is ofthen challenging. Several diagnostic guidelines exist, and many diagnostic modalities are recommended for diagnosis, although a gold standard is lacking. The full panel of diagnostic modalities includes, beside clinical history, anamnesis and laboratory tests, EMG, muscle ultrasound, MRI, muscle biopsy and determination of antibodies. We hypothesize that an evidence based diagnostic algorithm, using fewer and preferably the least invasive diagnostic modalities can approach the accuracy of the complete panel of diagnostic tests.

Study objective

We hypothesize that an evidence based diagnostic algorithm, using fewer and preferably the least invasive diagnostic modalities can approach the accuracy of the complete panel of diagnostic tests.

Study design

At baseline, 5 diagnostic tests will be performed, and a probability diagnosis (IIM yes/no) will be given. After six months, an expert panel will provide a reference diagnosis, based on the full diagnostic package + six months follow up.

Intervention

Full diagnostic panel: EMG, muscle ultrasound, muscle MRI, muscle biopsy, determination of antibodies

Contacts

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Eligibility criteria

Inclusion criteria

•Suspected idiopathic inflammatory myopathy •Symmetrical proximal muscle weakness causing functional limitation •Start of symptoms ≤24 months •Indication for treatment with corticosteroids •Minimum age of 18 years •Patient is mentally competent •Follow up of 6 months is possible

Exclusion criteria

• Other clear cause for proximal muscle weakness, i.e. the use of myotoxic medication, high suspicion for an inflammatory neuropathy (CIDP) or a positive family history for a hereditary neuromuscular disease • A high suspicion for sporadic inclusion body myositis (sIBM) • High suspicion on a neurogenic cause • Immunosuppressive treatment, with the exception of prednison up to 60mg since 2 weeks. • Previous history of myositis • Contraindications for MRI, claustrophobia • No consent for muscle biopsy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-06-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55232
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8764
CCMO	NL72219.018.19
OMON	NL-OMON55232

Study results