Towards an optimal diagnostic work-up in patients suspected for idiopathic inflammatory myopathies: a diagnostic accuracy study

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To construct an optimal diagnostic algorithm with the best possible accuracy, and the least patient burden, for patients suspected for idiopathic inflammatory myopathy who need treatment with corticosteroids.

Ethical review	Approved WMO
Status	Completed
Health condition type	Neuromuscular disorders
Study type	Observational invasive

Summary

ID

NL-OMON55232

Source
ToetsingOnline

Brief title
Optimization of diagnostic accuracy in IIMs

Condition

- Neuromuscular disorders

Synonym
muscle inflammation, Myositis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnostic accuracy, Diagnostic algorithm, Idiopathic inflammatory myopathy, Myositis

Outcome measures

Primary outcome

Diagnostic accuracy of various strategies, taking patient burden into account.

Secondary outcome

Costs of diagnostic tests in the respective testing strategies.

Study description

Background summary

Idiopathic inflammatory myopathies (IIMs) are a heterogeneous group of immune-related diseases, that need to be treated with prednisone (with the exception of sIBM). Because of heterogeneity, patients present with a range of clinical features, which makes it often hard to diagnose patients with this disease. Several diagnostic guidelines exist, and many diagnostic tools are recommended for diagnosis, although gold standard does not exist.
The full panel of diagnostic tools includes, beside clinical history, anamnesis and plane laboratory tests (including sCK), electromyography (EMG), muscle-ultrasound (US), MRI, (MRI guided) 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

To construct an optimal diagnostic algorithm with the best possible accuracy, and the least patient burden, for patients suspected for idiopathic inflammatory myopathy who need treatment with corticosteroids.

Study design

Prospective, fully paired diagnostic accuracy study, with a complete diagnostic

protocol for patients suspected of having idiopathic inflammatory myopathy with an indication for corticosteroid therapy.

Study burden and risks

Patients will be admitted to the neurology department for maximum 1.5 day. This will be out of patient care, so they don't neet to travel to the hospital five times, for five separate diagnostic tests. Thereby, diagnosis can be given at the end of these 1.5 dat, and patients can start treatment earlier.
The panel of diagnostic tests is equal to the normal diagnostic tests, with some variation between the Dutch hospitals. The risk of the diagnostic thest is equal to these test out of study context. The EMG is an unpleasant test, and takes about 30 minutes of time. Muscle ultrasound is a non-invasive diagnostic test. MRI is a safe radiologic test, the protocol takes about 30-45 minutes of time. The muscle biopsy is an invasive, sometimes painfull, but short intervention. It will be perfomed under local anesthesia. Risks of the muscle biopsy consist of infection and bleeding, but they rarely occur. Antibodies will be tested after venipuncture, 150uL is needed for the analysis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a patient must be adult (>=18 years of age) and suspected of an idiopathic inflammatory myopathy based on signs and symptoms. The latter include:
• Symmetrical proximal muscle weakness causing functional limitation to justify treatment with corticosteroids, without significant sensory abnormalities.
• Start of symptoms <=24 months

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) based on clinical symptoms, including: combination of slow onset of asymmetrically, predominantly distal weakness, atrophy of quadriceps and forearms and age >50 years.3
• High suspicion on a neurogenic cause, based on more severe distal weakness than proximal weakness, asymmetric weakness, fasciculations in >1 region
• No availability for follow-up of 6 months
• Immunosuppressive treatment
• Previous history of myositis
• Contraindications for MRI, claustrophobia
• No consent for muscle biopsy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	15-06-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	22-05-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2020
Application type:	Amendment
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

ID: 20832
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL72219.018.19