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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20832

Bron
NTR

Verkorte titel
ADAPT

Aandoening

Patients suspected of myositis

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Amsterdam UMC, locatie AMC
Hannah Walter

0205666889

Wetenschappelijk

Amsterdam UMC, locatie AMC
Hannah Walter

0205666889

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

•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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-06-2020
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-06-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55232
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten