IMMEDIATE study

Gepubliceerd: 01-12-2016 Laatst bijgewerkt: 18-08-2022

intravenous immunoglobulins will induce a fast and effective response in patients with newly diagnosed idiopathic inflammatory myopathies. Also, the treatment will be generally safe. Furthermore, this pilot study will show feasibility with respect...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25293

Bron
NTR

Verkorte titel
IMMEDIATE

Aandoening

- idiopathic inflammatory myopathies
- myositis (practical/clinical synonym)
- auto-immune disease
- neuromuscular disease

Ondersteuning

Primaire sponsor: Department of Neurology, Academic Medical Center Amsterdam
Overige ondersteuning: investigator initiated, funding by CSL Behring, Switzerland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to determine the number of participants with clinical significant

improvement (ACR/EULAR Total Improvement Score (TIS) of at least 40) at 9 weeks after start of IVIg treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Idiopathic inflammatory myopathies, inclusion body myositis excluded, are a group of treatable auto-immune disorders. Due to insufficient efficacy or side-effects of corticosteroids, additional immunosuppressive treatment is often needed. Clinical outcome is often disappointing, with many patients having a polyphasic and chronic clinical course. Relative under treatment in the first period resulting in irreversible damage, is thought to contribute to this. While not yet investigated, there are suggestions that early treatment with intravenous immunoglobulins might induce a fast response. We hypothesize that the use of early IVIg leads to fast improvement in newly diagnosed patients.

Objective:

Explore efficacy, safety and feasibility (with respect to a future trial) of early treatment with intravenous immunoglobulins for patients with idiopathic inflammatory myopathies.

Study design:

Investigator initiated, multicenter pilot study with an uncontrolled pre/posttest design.

Study population:

Twenty newly-diagnosed, treatment-naïve adult patients with idiopathic inflammatory myopathies (except inclusion body myositis).

Intervention:

Patients will be given a starting dose of intravenous immunoglobulins 2 gr/kg in 2-4 days and three maintenance treatments of 1 gr/kg thereafter every three weeks.

Main study parameters/endpoints:

The number of patients with clinical significant improvement, defined as ≥40% improvement on a continuous, weighted score of 6 core set measures (as developed by the International Myositis Assessment and Clinical Studies group) after 9 weeks of treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Structured risk analysis shows a moderate risk for patients.

Possible risks

• Side effects: treatment with intravenous immunoglobulins may lead to mild infusion reactions and rarely to serious adverse events such as thrombo-embolic events or hemolysis.

• Possible, temporary undertreatment: the uncertainty regarding efficacy of intravenous immunoglobulins may cause undertreatment in the first 9 week. However, we consider this temporary and adequately manageable with escape medication (consisting of standard corticosteroid therapy).

• Additional study related procedures: follow-up ancillary investigations (MRI, ultrasound, and laboratory investigations) and clinical visits for infusion of intravenous immunoglobulin are considered a minor inconvenience to study participants.

Possible benefits

• Beneficial side effect profile compared to standard treatment with corticosteroids.

• Faster and greater total clinical improvement compared to standard treatment with corticosteroids.

Doel van het onderzoek

intravenous immunoglobulins will induce a fast and effective response in patients with newly diagnosed idiopathic inflammatory myopathies. Also, the treatment will be generally safe. Furthermore, this pilot study will show feasibility with respect to a future phase 3 study.

Onderzoeksopzet

primary: after 9 weeks treatment

secondary

- efficacy: after 9 weeks treatment

- safety: during the total duration of the study

- feasibility: end of the study

Onderzoeksproduct en/of interventie

Study subjects will be treated with intravenous immunoglobulin (Privigen®). Initial dose of IVIg is 2 g/kg over 2-4 days, followed by 3 infusions of 1 g/kg on 1-2 days every 3 weeks

Contactpersonen

Publiek

Amsterdam UMC, University of Amsterdam, Amsterdam Neuroscience
Anneke Van der Kooi
Amsterdam
The Netherlands
T: 020 - 566 6889

Wetenschappelijk

Amsterdam UMC, University of Amsterdam, Amsterdam Neuroscience
Anneke Van der Kooi
Amsterdam
The Netherlands
T: 020 - 566 6889

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adult patients (age ≥ 18 years)

• Treatment naïve patients

• Subacute-onset of disease (disease duration of ≤ 9 months)

• Biopsy proven IIMs (see for diagnostic criteria Hoogendijk et al. 2004, note: ASS is considered a separate entity, but new criteria in which it has been included, has yet to be published).

o Dermatomyositis

o Polymyositis/overlap myositis/antisynthetase syndrome

o Immune-mediated necrotizing myopathy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• IVIg treatment related:

o Subjects who have received clinical relevant immunosuppressive medication (e.g. plasmapheresis, biologicals, immune therapy etc.) within the last 6 months

o history of thrombotic episodes within the 2 years prior to enrolment

o known allergic reactions or other severe reactions to any blood-derived product

o known IgA deficiency and anti-IgA serum antibodies

o pregnancy (wish).

• Conditions that are likely to interfere with:

o compliance (legal incompetent and/or incapacitated patients are excluded) or,

o evaluation of efficacy (e.g. due to severe pre-existing disability as result of any other disease than IIM).

• Lack of informed consent (IC)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-01-2017
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-12-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6029
NTR-old	NTR6160
Ander register	EudraCT: 2016-004766-26 : ABR: NL 58747

Resultaten