Intravenous versus subcutaneous immunoglobuline therapy in multifocal motor neuropathy

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Subcutaneous immunoglobuline therapy is as effective as intravenous immunoglobuline therapy in maintaining muscle strength in patients with multifocal motor neuropathy

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21709

Bron
NTR

Verkorte titel
ISIM

Aandoening

subcutaneous immunoglobuline therapy
Multifocal motor neuropathy
Intravenous immunoglobuline therapy
Dutch: subcutane immunoglobuline
Intraveneus immunoglobuline
Multifocale motorische neuropathy

Ondersteuning

Primaire sponsor: Department of neurology
Academical Medical Centre, Amsterdam
Meibergdreef 9, 1100 DD Amsterdam
020-5669111
Overige ondersteuning: Department of neurology
Sanquin, pharmaceutical company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is maintaining the muscle strength after switching to subcutaneous immunoglobuline measured according to the Medical Research Counsil scale (MRC score). The MRC score will be measured during baseline visits (between 2 consecutive intravenous immunoglobuline treatment). After the switch to subcutaneous immunoglobuline MRC score is determined at 1, 2, 3, 4, 6 weeks and 3 4 and 6 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Multifocal motor neuropathy (MMN) is a rare immune mediated disorder characterized by slowly progressive, asymmetric, predominantly distal weakness of one or more limbs without sensory loss. Intravenous immunoglobuline (IVIg) is the first line treatment when disability is sufficiently severe to warrant treatment. An alternative route of immunoglobulin administration is subcutaneous immunoglobulin (SCIg), used in patients with immuno-deficiency syndromes. Our hypothesis is that SCIg therapy is as effective as IVIg therapy in maintaining muscle strength in patients with MMN. Patiens using IVIg will switch to SCIg and will be followed for at least 6 months in which muscle stregth, disability, side effects and immunoglobuline serum levels will be assessed.

Doel van het onderzoek

Subcutaneous immunoglobuline therapy is as effective as intravenous immunoglobuline therapy in maintaining muscle strength in patients with multifocal motor neuropathy

Onderzoeksproduct en/of interventie

Patients already treated with (different) intravenous immunoglobuline will switch to weekly subcutaneous immunoglobuline (Gammaquin, Sanquin, registered in the Netherlands under RVG 16941). This treatment will be continued for 6 months. After reaching the end of the study patients are allowed to choose between both treatments which they will continue.

Contactpersonen

Publiek

Academical Medical Centre
Department of Neurology
F. Eftimov
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 20-5669111

Wetenschappelijk

Academical Medical Centre
Department of Neurology
F. Eftimov
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 20-5669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All adult patients (> 18 years) with signs and symptoms consistent with MMN that fulfill the EFNS/PNS criteria for definite MMN and are being treated with IVIg for at least 6 months at regular intervals of at most 6 weeks. Patients have to have stable disease for at least 6 months before inclusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of drugs which are known to cause motor neuropathy;
2. Patient and/or partner is/are unable to administer SCIg at home;
3. Other diseases known to cause neuropathy or to reduce mobility;
4. Diseases known to lead to severe handicap or death at short notice;
5. A known selective IgA deficiency with anti-IgA antibodies;
6. Refusal to give informed consent or withdrawal of previously given permission;
7. Legally incompetent adult

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2007
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-05-2007
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	NL949
NTR-old	NTR974
Ander register	:
ISRCTN	ISRCTN66618743

Resultaten

Samenvatting resultaten
The writing commettee will consist of F. Eftimov, I.N. van Schaik, R. de Haan and M. Vermeulen.