Intravenous versus subcutaneous immunoglobuline therapy in multifocal motor neuropathy

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21709

Source
NTR

Brief title
ISIM

Health condition

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

Sponsors and support

Primary sponsor: Department of neurology
Academical Medical Centre, Amsterdam
Meibergdreef 9, 1100 DD Amsterdam
020-5669111
Source(s) of monetary or material Support: Department of neurology
Sanquin, pharmaceutical company

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Grip strength
2. Functional dexterity test
3. Amsterdam Linear disability scale (ALDS)
4. INCAT disability scale
5. SF-36
6. Modified Life Quality index
7. Any adverse event or reaction
8. IgG and IgG subclass peak and trough levels

Study description

Background summary

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.

Study objective

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-05-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL949
NTR-old	NTR974
Other	:
ISRCTN	ISRCTN66618743

Study results

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