ISRCTN66618743 https://doi.org/10.1186/ISRCTN66618743

Intravenous versus subcutaneous immunoglobulin therapy in multifocal motor neuropathy

Submission date	Recruitment status	[ ] Prospectively registered
27/06/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/06/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/10/2021	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Intravenous versus subcutaneous immunoglobulin therapy in multifocal motor neuropathy

Acronym
ISIM

Study objectives
Subcutaneous immunoglobulin (SCIg) therapy is as effective as intravenous immunoglobulin (IVIg) therapy in maintaining muscle strength in patients with Multifocal Motor Neuropathy (MMN).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee (Medisch Ethische Commissie) on the 3rd May 2007 (ref: MEC 07/101 # 07.17.0662).

Study design
Interventional crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intravenous or subcutaneous immunoglobulin therapy, multifocal motor neuropathy

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Subcutaneous immunoglobulin (Gammaquin)

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

Key secondary outcome(s))

1. Grip strength, measured at 1, 2, 3, 4, 6 weeks and 3, 4 and 6 months
2. Functional dexterity test, measured at 3 months and at 6 months
3. Amsterdam Linear Disability Scale (ALDS), measured at 3 months and at 6 months
4. Inflammatory Neuropathy Cause and Treatment (INCAT) disability scale, measured at 3 months and at 6 months
5. 36-item Short Form health survey (SF-36), measured at 3 months and at 6 months
6. Modified Life Quality index, measured at 3 months and at 6 months
7. Any adverse event or reaction, measured at 1, 2, 3, 4, 6 weeks and 3, 4 and 6 months
8. Immunoglobulin G (IgG) and IgG subclass peak and trough levels, measured at 1, 2, 3, 4, 6 weeks and 3, 4 and 6 months

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. All adult patients (greater than 18 years) with signs and symptoms consistent with MMN that fulfill the European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) criteria for definite MMN and are being treated with IVIg for at least six months at regular intervals of at most six weeks
2. Patients have to have stable disease for at least six months before inclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key 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 Immunoglobulin A (IgA) deficiency with anti-IgA antibodies
6. Refusal to give informed consent or withdrawal of previously given permission
7. Legally incompetent adult

Date of first enrolment
01/06/2007

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sanquin Blood Bank (The Netherlands)

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration