

Intravenous versus subcutaneous immunoglobulin therapy in multifocal motor neuropathy

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/06/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

10

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)

Sponsor details

Department of Neurology

PO Box 22660

Amsterdam

Netherlands

1100 DD

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration