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Intravenous versus subcutaneous immunoglobulin therapy in multifocal motor neuropathy

Submission date
27/06/2007

Registration date
27/06/2007

Last Edited
07/10/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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