# Intravenous versus Subcutaneous Immunoglobuline therapy in Multifocal motor neuropathy

Published: 12-07-2007
Last updated: 08-05-2024

1. Primary objective:To evaluate whether subcutaneous immunoglobulin infusion is as effective as intravenous immunoglobulin in maintaining muscle strength in patients with multifocal motor neuropathy.2. Secondary objective:a) To evaluate whether...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Peripheral neuropathies |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON31197

**Source**
ToetsingOnline

**Brief title**
ISIM

### Condition

- Peripheral neuropathies

**Synonym**
motor neuropathy, nerve damage

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,bedrijf,Sanquin

## Intervention

**Keyword:** immunoglobuline, intravenous, multifocal motor neuropathy, subcutaneous

## Outcome measures

### Primary outcome

The primary outcome is defined as the proportion of patients who deteriorate

more than 1 point in the MRC (Medical Research Council) sum score during SCIg

treatment as compared with IVIg treatment.

### Secondary outcome

Secondary study parameters

1. grip strength

2. functional dexterity test

3. 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 considered to be the first line treatment when disability is sufficiently

severe to warrant treatment. Subcutaneous administration of immunoglobuline (SCIg) seems to be a good alternative route. SCIg is often administered in patients with immuno-deficiency syndromes with low or absent antibody production.
Several advantages of SCIg have been reported.
Firstly, weekly SCIg administration produces a stable day-by-day concentration of IgG. Based on the hypothesis that in MMN patients there is an ongoing immunological process, a stable concentration would be preferable above alternating peak and trough levels.
Secondly, SCIg avoids unphysiologically high serum IgG peak levels as produced by IVIg which are thought to be responsible for some adverse effects.
Thirdly, as SCIg can be administered by the patients themselves, the switch to SCIg improves health-dependent quality of life and treatment satisfaction.
Finally, SCIg is less expensive.

## Study objective

1. Primary objective:

To evaluate whether subcutaneous immunoglobulin infusion is as effective as intravenous immunoglobulin in maintaining muscle strength in patients with multifocal motor neuropathy.

2. Secondary objective:

a) To evaluate whether SCIg is as effective as IVIg in maintaining grip strength.
b) To evaluate whether SCIg is as effective as IVIg in maintaining functional status.
c) To evaluate whether SCIg results in a higher level of perceived quality of life.
d) Assessment of the potential (serious) adverse events, adverse reactions and suspected unexpected adverse reactions of SCIg, especially local tissue reaction.
e) To evaluate whether SCIg results in more stable and higher mean IgG serum levels compared to IVIg.

## Study design

A single-centre open-label pilot intervention study

## Intervention

After informed consent and baseline assessments, all patients will receive subcutaneous immunoglobuline (SCIg, Gammaquin) one week after the second IVIg treatment. Patients shall be instructed how to adminster the SCIg treatments

themselves. SCIg will be administered once a week.
Gammaquin consists of a protein-fraction extracted from normal, human plasma from at least 1000 donors. Gammaquin contains 160mg/ml protein of which at least 90% is immunoglobuline G (IgG).
For each patient the monthly IVIg dosis will be assessed at baseline. The weekly SCIg dosis will be calculated for each individual patient, so that approximately half of the IVIg dosis that a patient normally receives is given subcutaneously. If a patient deteriorates on the starting dose, the dose will be doubled the next week.

**Study burden and risks**

The next items will be assessed:
- Weight: first visit
- Two disability checklists: first 2 visits, 3 month, end of study
- Two quality of life questionnaire: first 2 visits, 3 month, end of study
- Adverse events questionnaire: all 11 visits
- Assessment of muscle strength, grip strength and hand function tests: all 11 visits
- Blood samples by finger-prick: all 11 visits (13 times)

The finger-prick is an easy and the least invasive method to determine serum immunoglobuline concetration.

Local adverse events (redness, itch and pain) are often reported with SCIg. These reactions were transient and most patients did not perceive them as troublesome. One of the objectives of this study is to assess the frequency and intensity of these adverse events.

# Contacts

**Public**
Academisch Medisch Centrum

Meibergdreef 9
1100DD Amsterdam
Nederland
**Scientific**
Academisch Medisch Centrum

Meibergdreef 9
1100DD Amsterdam
Nederland

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## 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

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

# Study design

## Design

| | |
|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |

| | |
|---|---|
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2007 |
| Enrollment: | 10 |
| Type: | Anticipated |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | Gammaquin |
| Generic name: | subcutaneous immunoglobuline |
| Registration: | Yes - NL outside intended use |

## Ethics review

Approved WMO

| | |
|---|---|
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 |
|---|---|
| EudraCT | EUCTR2007-001797-86-NL |
| CCMO | NL17216.018.07 |