Inflammatory Neuropathies: the Mechanism of Intravenous Immunoglobulin

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-To evaluate the effects of IVIg on the humoral and cellular immune system.-To identify biomarkers which are associated with the effect (on muscle strength and sensory modalities) of IVIg. To investigate the value of these biomarkers in other...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON31804

Source
ToetsingOnline

Brief title
Inflammatory Neuropathies and IVIg

Condition

- Autoimmune disorders
- Peripheral neuropathies

Synonym
autoimmune neuropathy/ nerve inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: PBF

Intervention

Keyword: Immune system, Immunoglobulin, Inflammatory, Neuropathy

Outcome measures

Primary outcome

The effect of IVIg on muscle strength and sensory modalities will be measured by comparing neurological examination after treatment (t=5, t=19, t=33) with neurological examination before treatment (t=1).

The effects of IVIg treatment on complement component concentration will be measured in every serum sample to monitor the activity of this part of the humoral immune system before, during and after treatment.

mRNA will be isolated from blood samples before and after treatment to obtain information about the influence of IVIg on leukocytes, create gene expression profiles and to observe whether there is a difference in expression before and after treatment (concerns cellular immune system).

To analyze the sera in more detail, proteomics technology will be used. Surface enhanced laser desorption ionization time of flight (SELDI TOF) analysis allows reproducible measurements in large amounts of sera and is the most powerful method for biomarker identification at this moment.

Secondary outcome

Adverse effects

Study description

Background summary

Intravenous immunoglobulins (IVIg) are known to be efficacious in many inflammatory and autoimmune diseases. The activity of IVIg is complex and incompletely understood; it involves effects on the cellular and humoral immune system. Inflammatory neuropathies include Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy (MMN). These three polyneuropathies are presumed to be caused by immunemediated demyelination. The treatment of choice for patients with GBS and MMN is administration of IVIg. A significant percentage CIDP patient responds favorably to IVIg. Muscle strength increases and sensory loss decreases. MMN and CIDP patients are often treated with maintenance treatment. Our aim is to evaluate the effects of IVIg on the humoral and cellular immune system and to identify biomarkers to increase the understanding about the mechanism and strive for improvement of treatment in the future. Furthermore we want to investigate the value of these biomarkers in other immunemediated neuropathies.

Study objective

-To evaluate the effects of IVIg on the humoral and cellular immune system.

-To identify biomarkers which are associated with the effect (on muscle strength and sensory modalities) of IVIg. To investigate the value of these biomarkers in other immunemediated neuropathies.

Study design

Monocenter prospective cohort study for a period of three years

Intervention

Patients with GBS, CIDP and MMN will be treated according to the protocol of the UMC Utrecht. These patients receive a cumulative dose of 2g/kg in 5 consecutive days. Neurological examination will be performed before and after treatment (t=1, t=5, t=19, t=33). At neurological examination the sensory modalities touch, pain, vibration and position sense will be tested and muscle strength will be tested by manual muscle testing bilaterally in arm and leg (in total 20 muscles/ muscle groups, MRC grading) and by hand-held dynamometry. Blood samples will be taken every day during treatment plus two and four weeks after treatment (t=19, t=33).

Study burden and risks

The burden includes five venous punctures in five days followed by two venous punctures two and four weeks after treatment. There is a risk in developing a

hematoma at the puncture site.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age > 18 years
Patients with GBS. Patients with CIDP (exacerbation) and MMN who were not treated at least three months prior to inclusion.

Exclusion criteria

Other neuropathies (e.g. diabetic, porphiric, intoxication with medication or metal, vasculitic,

Lyme neuroborreliosis, post-radiation, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies). Patients with an anaphylactic reaction to IVIg in the past.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL17346.041.07