A Randomized controlled trial comparing two different immunoglobulins in the treatment of CIDP.

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To investigate if:-Kiovig is at least as effective as Gammagard. (equivalence)-Kiovig has a good side effect profile for CIDP patients.-Whether patients prefer Kiovig to Gammagard.

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

Summary

ID

NL-OMON31412

Source
ToetsingOnline

Brief title
Comparing immunoglobulins in CIDP: CIC study

Condition

- Autoimmune disorders
- Peripheral neuropathies

Synonym
peripheral nerve lesion, polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Baxter,firma baxter

Intervention

Keyword: CIDP, immunoglobulin, polyneuropathy, treatment

Outcome measures

Primary outcome

The efficacy: the ODSS will be used as the primary outcomescale. A change of more than one point on the ODSS from baseline will be considered as improvement or worsening. A change of mean ODSS between the two groups of 1 point or less will be seen as equivalence. The vigorimeter and the MRC sumscore will be used as secondary outcome measurements.

Secondary outcome

The secondary objective will be to record the occurence of side-effects and the preferences of patients regarding the medication.

Study description

Background summary

CIDP is a rare nerve disorder leading to a loss of strength and sensibility. Intravenous immuunglobulins are proven to be effective in the treatment of CIDP. In practise CIDP patients are treated with different brands of immunoglobulins, (depending on what is available) that are considered to have comparable efficacy, although this has not been formally investigated. In practise CIDP patients often report that some IVIg brands are more effective than others. Kiovig is a registered immuunglobuline brand which is easy to administer and can be infused faster than other immunoglobulines. A shorter infusion time is preferable because most CIDP patients need long term treatment.

Study objective

To investigate if:
-Kiovig is at least as effective as Gammagard. (equivalence)
-Kiovig has a good side effect profile for CIDP patients.

-Whether patients prefer Kiovig to Gammagard.

Study design

Patients are given Kiovig instead of Gammagard, the dose and dose-interval will be the same. Neurological examination, squeeze strength and questionnaires are used to show if Kiovig is as effective as Gammagard. Side-effects and patient preference are recorded. The first part of the study is a randomized dubbel-blind study, where patients receive either Gammagard or Kiovig. The second part of the study is an open-label phase where all patients receive Kiovig treatment.

Intervention

The first group will receive a brand of immunoglobulin; Gammagard. The individual dosage and dosage-interval will be used.
the second group will receive another brand of immunoglobulin; kiovig. Again the dosage and dosage-interval will be kept the same.

Study burden and risks

Because Kiovig is a registered immunoglobuline the side-effects will be similar as Gammagard. The patients burden is small, six Neurological examinations and the completion of some simple questionnaires.

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

minimum age of 18 years, improvement of muscle function after start Gammagard, active illness, ongoing intermittent treatment with a stable Gammagard dose. clinical and EMG findings compatible with CIDP

Exclusion criteria

IgA deficiency or allergic reactions to IVIg. Hereditary neuropathy or severe concomittant illness. MMN. atypical CIDP.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	31-12-2007
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Gammagard S/D
Generic name:	Immunoglobuline
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Kiovig
Generic name:	Immunoglobuline
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	22-05-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-10-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-12-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2007-001777-29-NL
ISRCTN	ISRCTN52121370
CCMO	NL16730.078.07