

A randomised controlled trial comparing two different immunoglobulins in the treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Submission date 16/07/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/12/2020	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr K. Kuitwaard

Contact details
Erasmus Medisch Centrum
Department Neurology
Room H 673
Rotterdam
Netherlands
3000 CA
+31 (0)10 408 8209
k.kuitwaard@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised controlled trial comparing two different immunoglobulins in the treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Acronym

CIC study

Study objectives

Is Kiovig as effective as Gammagard in the treatment of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) symptoms?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethical Committee of the Erasmus Medical Centre on the 10th October 2007.

Study design

Multicentre, randomised, double blinded, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Interventions

The investigational product is Kiovig a brand of immunoglobulin. Kiovig will be compared to Gammagard (another brand of immunoglobulin).

The first phase is a randomised double-blind phase, where patients receive one infusion of Gammagard, followed by four blind gifts (Gammagard or Kiovig).

The second phase is an open-label phase where all patients receive five gifts of Kiovig.

Please note that after medical ethics approval, the start and end dates of this trial have been moved forward. The previous anticipated dates of this trial were:

Anticipated start date: 01/09/2007

Anticipated end date: 01/05/2008

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Kiovig, Gammagard

Primary outcome measure

1. Efficacy: the Overall Disability Sum Score (ODSS) will be used as the primary outcome scale. A change of more than one point will be considered as improvement or worsening
2. The vigorimeter and Medical Research Council (MRC) sum score will be used as secondary outcome scales

Secondary outcome measures

1. The occurrence of side-effects
2. The preferences of patients regarding the medication

Overall study start date

01/11/2007

Completion date

01/10/2008

Eligibility

Key inclusion criteria

1. Minimum age 18 years
2. Improvement of muscle function after start Gammagard
3. Active illness
4. Ongoing intermittent treatment with a stable Gammagard dose
5. Clinical and Electromyography (EMG) findings compatible with CIDP

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

25

Total final enrolment

27

Key exclusion criteria

1. Immunoglobulin A (IgA) deficiency or allergic reactions to Intravenous Immunoglobulin (IVIg)
2. Hereditary neuropathy or severe concomitant illness
3. Multifocal Motor neuropathy (MMn), atypical CIDP

Date of first enrolment

01/11/2007

Date of final enrolment

01/10/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Erasmus Medisch Centrum

Rotterdam

Netherlands

3000 CA

Sponsor information**Organisation**

Erasmus Medical Centre (The Netherlands)

Sponsor details

Department of Neurology

P.O. Box 2040

Rotterdam

Netherlands

3000 CA

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/content/englishindex.htm>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Industry

Funder Name

Baxter B.V. (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010	31/12/2020	Yes	No