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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

Registration date
16/07/2007

Overall study status
Completed

Last Edited
31/12/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

Study type(s)
Treatment

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 approva, 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(s)
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

Key secondary outcome(s))
1. The occurrence of side-effects
2. The preferences of patients regarding the medication

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Baxter B.V. (The Netherlands)

Results and Publications

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