ISRCTN66955626 https://doi.org/10.1186/ISRCTN66955626

Subcutaneous application of gammanorm®

Submission date 30/05/2014	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/09/2014	**Overall study status** Completed	
Last Edited 30/09/2014	**Condition category** Haematological Disorders	

Plain English summary of protocol

Background and study aims
An antibody is a protein made by the immune system that recognises harmful substances in the body, such as bacteria and viruses, and neutralises them. Gammanorm® is a human immunoglobulin medicine that contains a number of antibodies and is given as an injection to treat people that have immune systems that produce few antibodies; these include patients with congenital or acquired antibody deficiencies. We want to find out more about the daily routine use of gammanorm® and get information about patient satisfaction and health-related quality of life during therapy.

Who can participate?
Patients of any age and gender that are treated with gammanorm®.

What does the study involve?
Doctors that have patients being treated with gammanorm® document, or record, information about those patients. This includes gathering data about how the patient takes their medicine, the disease they are suffering from, their age, gender, weight, any other medicine they are taking or any other illnesses that they have. No special investigations or procedures need to be done and it does not interfere with the patient's usual treatment as prescribed by the doctor. In order to get information about the health-related quality of life, patients are asked by their doctors to fill in a questionnaire at the beginning of the study and then every six months for up to 2 years.

What are the possible benefits and risks of participating?
The data will help to build up detailed knowledge about the subcutaneous route (that is, injection) of immunoglobulin treatment, especially regarding the patient's satisfaction and health-related quality of life. Gammanorm® is a registered product, the possible side-effects are described in the package insert.

Where is the study run from?
The trial takes place in about 30 study centres in Germany.

When is study starting and how long is it expected to run for?
June 2014 to May 2018

Who is funding the study?
Octapharma GmbH (Germany)

Who is the main contact?
Dr. Anette Debes
anette.debes@octapharma.de

Contact information

Type(s)
Scientific

Contact name
Dr Axel Jansink

Contact details
Elisabeth-Selbert-Str. 11
Langenfeld
Germany
40764

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GAN-04

Study information

Scientific Title
Non-interventional study on the subcutaneous application of gammanorm®

Study objectives
Home-based subcutaneous treatment with gammanorm® improves patient's satisfaction and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at the time of registration

Study design
Non-interventional, prospective, multi-centre, observational study

Primary study design
Observational

Secondary study design
Multi-centre

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Primary immunodeficiency syndromes/severe secondary hypogammaglobulinaemia

Interventions
Treatment with gammanorm in routine clinical use will be documented. This includes data about the patient's disease, age, gender, weight, concomitant medication or illness and information about the application. If available, laboratory data about the efficacy of treatment should also be documented. Information about quality of life will be documented at the beginning and every six months. Each patient can be documented for a maximum of 2 years. No special or additional investigations must be initiated for the purpose of this non-interventional study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Information about the treatment with gammanorm® in home therapy and the health-related quality of life will collected by using CRFs and appropriate questionnaires (SF-36 and CHQ-PF50).

Secondary outcome measures
Efficacy of treatment will be measured by evaluating laboratory data, if available.

Overall study start date
01/06/2014

Completion date
31/05/2018

Eligibility

Key inclusion criteria
Patients of any gender and age, who receive treatment with gammanorm®

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
100

Key exclusion criteria
Hypersensitivity to any of the components

Date of first enrolment
01/06/2014

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
Germany

Study participating centre
Elisabeth-Selbert-Str. 11
Langenfeld
Germany
40764

Sponsor information

Organisation
Octapharma GmbH (Germany)

Sponsor details
Elisabeth-Selbert-Str. 11
Langenfeld
Germany
40764

Sponsor type
Industry

ROR
https://ror.org/002k5fe57

Funder(s)

Funder type
Industry

Funder Name
Octapharma GmbH (Germany)

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