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# Comparison of quality of life and satisfaction in primary immunodeficient patients treated with subcutaneous injections of Gammanorm administered using a pump or a syringe for rapid manual administration

**Submission date**
02/09/2015

**Recruitment status**
No longer recruiting

**Registration date**
15/12/2015

**Overall study status**
Completed

**Last Edited**
28/06/2019

**Condition category**
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Primary immunodeficiency disorders (PID) are caused by an inherited defect in the immune system, which makes a person more susceptible to infection. There are more than 200 of these disorders, the symptoms of which can vary greatly, ranging from very mild or non-existent (asymptomatic) to severe and debilitating. Gamma globulins are proteins found in the blood plasma. There are different types of gamma globulins, but the most important are immunoglobulins, also known as antibodies. The immune system uses antibodies to recognize and fight infections. In many of the PID's, people do not have enough of these gamma globulins in their blood, and so are given injections of immunoglobulins to help strengthen their immune systems. When a patient receives this treatment, the injections are often done by the patient themselves at home. The injections can be given using a syringe or an automatic pump (which delivers the dose automatically over a period of time). This study aims to find out whether patients are happier using a syringe or an automatic pump method for receiving their injections.

Who can participate?
Adults with primary immunodeficiency who have received injections of immunoglobulin at use using an automatic pump or syringe for at least one month.

What does the study involve?
Participants are randomly assigned into two groups, each of which receives the treatments in a different order. Each patient is treated for three months with the first treatment option, and then treated for 3 months with the second treatment option (i.e. syringe and then pump, or pump and then syringe). Patients complete a questionnaire about how satisfied they are with each of the treatment options at the end of each three month treatment period.

What are the possible benefits and risks of participating?
Participants will benefit from learning a new technique for administering their immunoglobulin treatment at home, which could be preferable than their current technique. Risks of participating involve the minor risks associated with repeated blood tests, such as pain, bruising or infection.

Where is the study run from?
1. University Medical Center Freiburg (Germany)
2. Klinikum St. Georg (Germany)
3. University Hospital of Wales (UK)
4. Derriford Hospital (UK)
5. The Royal London Hospital (UK)
6. University Hospitals Birmingham (UK)
7. Padova Hospital (Italy)
8. John Radcliffe Hospital, Oxford (UK)
9. Royal Free London Hospital (UK)
10. Campbell Town Hospital (Australia)
11. Canberra Hospital (Australia)
12. Università di Roma "Sapienza", Policlinic Umberto I, Rome (Italy)

When is the study starting and how long is it expected to run for?
November 2014 to December 2017

Who is funding the study?
Octapharma (Austria)

Who is the main contact?
Tatiana Lavrova
tatiana.lavrova@octapharma.com

# Contact information

### Type(s)
Scientific

### Contact name
Dr Tatiana Lavrova

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# Additional identifiers

### EudraCT/CTIS number
2014-003746-27

### IRAS number

### ClinicalTrials.gov number
NCT02503293

### Secondary identifying numbers
GAN-06

# Study information

### Scientific Title
A randomised, cross-over study to compare quality of life and satisfaction in primary immunodeficient patients treated with subcutaneous injections of Gammanorm® 165 mg/mL administered with two different delivery devices: injections using pump or rapid push

### Acronym
GAN-06

### Study objectives
The administration of Gammanorm 165 mg/ml using a syringe is not inferior to the administration of Gammanorm 165 mg/ml using a pump regarding patient satisfaction.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Central Ethics Committee, Albert Ludwig University(Germany), 09/02/2015, ref: 561/14(FF-MC)
2. Research Ethics Service, Wales (UK), 12/06/2015, ref: 15/WA/0047
3. Comitato Etico per la Sperimentazione Clinica della Provincia di Padova, 21/04/2016, ref: NRC AOP0707
4. ACT Health, Research Ethics and Governance Office, 21/06/2016, ref: ETH.6.16.113E
5. South Western Sydney Local Health District, 30/05/2016; ref: HREC/16/LPOOL/44
6. Ethics Committee University "Sapienza", 03/03/2017, ref: 4359

### Study design
A non-inferiority comparative interventional multi-centre prospective longitudinal randomised open-label cross-over study

### Primary study design
Interventional

### Secondary study design
Randomised cross over trial

### Study setting(s)
Hospital

### Study type(s)
Quality of life

## 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

## Interventions
Participants are randomly allocated to one of two groups, who receive the two different treatments in a different order (pump then syringe or syringe then pump). Treatment will be administered subcutaneously at home by the patient.

Pump treatment: The usual dose is 0.6 mL (100 mg) of Gammanorm® 165 mg/mL per kg of body weight once a week, which can be administered at several infusion sites.

Syringe treatment: The usual dose is 0.6 mL (100 mg) of Gammanorm® 165 mg/mL per kg of body weight per week. The weekly dose could be divided into three injections administered every other day at a single infusion site.

Participants use the pump treatment and the syringe treatment for a total of three months, with no wash-out period in between.

## Intervention Type
Drug

## Phase
Phase III/IV

## Drug/device/biological/vaccine name(s)
Gammanorm

## Primary outcome measure
Patient satisfaction is measured using the life quality index (LQI) questionnaire at the end of each 3 month treatment period.

## Secondary outcome measures
1. Therapy-related problems and therapy setting is measured using LQI sub-scores at baseline, 3 months and 6 months
2. Patient satisfaction is measured using the Treatment Satisfaction Questionnaire for Medication (TSQM-11) at baseline, 3 months and 6 months
3. Patient preference is measured by patient answer at 6 months
4. Efficacy (clinical efficacy and residual levels of IgG) of Gammanorm® 165 mg/mL is measured by evaluation of IgE level at baseline, 3 months and 6 months
5. Systemic and local tolerability of Gammanorm® 165 mg/mL is measured by evaluation of the diary and AE Reporting during ongoing study
6. Burden of illness is measured using the PRISM test at at baseline, 3 months and 6 months
7. Burden of subcutaneous immunoglobulin treatment delivery device is measured using the PRISM test at at baseline, 3 months and 6 months
8. Costs measured by analyses of the patient diary at 6 months

## Overall study start date

26/11/2014

### Completion date
11/12/2017

## Eligibility

### Key inclusion criteria
1. Adult patients (≥ 18 years).
2. Presenting with primary immunodeficiency.
3. Having received subcutaneous injections of immunoglobulin at home using an automatic pump or syringe for at least 1 month at the time of inclusion.
4. For whom the investigator decides to maintain immunoglobulin replacement therapy with subcutaneous injections of Gammanorm® 165 mg/mL at home.
5. Women of childbearing potential must have a negative result on a pregnancy test (human chorionic gonadotropine [HCG]-based assay) and need to practice contraception using a method of proven reliability for the duration of the study

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
A minimum of 30 patients, but not more than 40 patients will be enrolled in the study.

### Total final enrolment
30

### Key exclusion criteria
Participating in another interventional clinical study and receiving investigational medicinal product within three months before study entry.

### Date of first enrolment
25/06/2015

### Date of final enrolment
14/07/2017

## Locations

### Countries of recruitment
Australia

England

Germany

Italy

United Kingdom

Wales

**Study participating centre**
**University Medical Center Freiburg**
Centre of Chronic Immunodeficiency
Breisacher Straße 117
Freiburg
Germany
79106

**Study participating centre**
**Klinikum St. Georg**
Delitzscher Street 141
Leipzig
Germany
04129

**Study participating centre**
**University Hospital of Wales**
Dept. of Biochemistry & Immunology
Heath Park
Cardiff
United Kingdom
CF14 4XW

**Study participating centre**
**Derriford Hospital**
Department of Immunology and Allergy
Eden Unit, level 7
Derriford Road
Plymouth
United Kingdom
PL6 8DH

**Study participating centre**
**The Royal London Hospital**
Barts Health NHS Trust
4th Floor Pathology & Pharmacy Building
80 Newark Street
London
United Kingdom
E1 2ES

**Study participating centre**
**University Hospitals Birmingham**
Department of Immunology
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

**Study participating centre**
**Padova Hospital (Azienda Ospedaliera di Padova)**
Dipartimento di Medicina (DIMED)
Via N. Giustiniani, 2
Padova
Italy
35128

**Study participating centre**
**John Radcliff Hospital**
Department of Clinical Immunology
Oxford
United Kingdom
OX3 9DU

**Study participating centre**
**Royal Free London Hospital**
Department of Immunology
London
United Kingdom
NW3 2QG

**Study participating centre**
**Campell Town Hospital**
Unit Immunology and Allergy
Therry Road
Campell Town
Australia
NSW 2560

**Study participating centre**
**Canberra Hospital**
Yamba Dr.
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ACT 2605

**Study participating centre**
**Università di Roma "Sapienza"**
Policlinic Umberto I
Viale del Policlinico, 155
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# Sponsor information

**Organisation**
Octapharma Pharmazeutika Prod.Ges.m.b.H.

**Sponsor details**
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**Sponsor type**
Industry

**Website**
www.octapharma.com

**ROR**

https://ror.org/022k50n33

# Funder(s)

**Funder type**
Industry

**Funder Name**
Octapharma

# Results and Publications

**Publication and dissemination plan**
A clinical study report complying with relevant guidelines will be written following statistical analyses. This document will be reviewed and approved by the Sponsor and the principal investigator.

**Intention to publish date**
31/12/2018

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | 08/02/2019 | 08/02/2019 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |