Pharmacokinetics and safety of the intravenous human immunoglobulin product Nanogam 100 mg/ml

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune system disorders congenital
Study type	Interventional

Summary

ID

NL-OMON38799

Source
ToetsingOnline

Brief title
PK and safety of Nanogam 100 mg/ml

Condition

- Immune system disorders congenital
- Immunodeficiency syndromes

Synonym
congenital antibody immune disorder, primary hypogammaglobulinemia

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedvoorziening
Source(s) of monetary or material Support: Sanquin Bloedvoorziening

Intervention

Keyword: 10% IVIG, intravenous immunoglobulin, pharmacokinetics

Outcome measures

Primary outcome

The main study parameters are the plasma concentration-time curve, half-life, area under the curve (AUC), volume of distribution (Vd), Cmax, Tmax, and elimination rate constant(s) are calculated. PK parameters obtained with the Nanogam 50 mg/ml and Nanogam 100 mg/ml will be compared.

Secondary outcome

Safety will be monitored by measuring vital signs and recording all adverse events during and after the infusions (number and type).

Study description

Background summary

Intravenous immunoglobulin (IVIG) is used for treatment of a heterogeneous group of immune related diseases both in immune-replacement therapy and in immune-modulating disorders. Sanquin developed a 100 mg/ml IVIg product manufactured according to the Nanogam 50 mg/ml process.

Study objective

The primary objective is to examine the pharmacokinetics of Nanogam 100 mg/ml and compare these with Nanogam 50 mg/ml. The secondary objective is safety and tolerability of Nanogam 100 mg/ml. Aim is to show bioequivalency between Nanogam 50 mg/ml and Nanogam 100 mg/ml.

Study design

The study is a prospective, open-label, cross-over, multicentre trail.

Intervention

Patients will receive one intravenous infusion with Nanogam 50 mg/ml as they used to and four infusions of Nanogam 100 mg/ml at frequency and dose as their regular treatment with Nanogam 50 mg/ml.

Study burden and risks

Patients are already stabilised on treatment with Nanogam 50 mg/ml. Patients will receive one intravenous infusion with Nanogam 50 mg/ml as they used to and four intravenous infusions with Nanogam 100 mg/ml at the frequency and dose as their regular treatment. Since both products are the same except for the protein concentration, no extra risks are expected. Patients who used to be treated via the home treatment service have to visit the hospital to be treated with the study medication. Extra blood samples will be taken. Prior to each infusion a blood sample (5 ml) is taken to determine IgG trough level. After the first (Nanogam 50 mg/ml) and the fifth infusion (Nanogam 100 mg/ml) blood samples for pharmacokinetic analysis (9 times 5 ml) are drawn directly after infusion and 1 hour, 2 hours and 1, 2, 3, 7, 14 and 21 days after infusion. Patients will be asked to stay in the hospital till 2 hours after infusion for two blood samplings. Haematology and clinical chemistry variables will be determined before and directly after each infusion with Nanogam 100 mg/ml (2x 10 ml). Extra renal function (serum creatinin) (2 ml) will be monitored on day 1, 2 and 3 after the fifth infusion. Vital signs are measured before infusion, and 30 min, 60 min and thereafter with one-hour intervals during the infusion and directly after the infusion with Nanogam 100 mg/ml. A pre-treatment serum and EDTA-plasma sample (5 ml each) before the first Nanogam 100 mg/ml infusion will be stored at -70 ºC by Sanquin for possible future testing of virus infection.

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

- Primary a- or hypogammaglobulinemia, particularly patients with XLA or CVID
- Stabilised on treatment with Nanogam (50 mg/ml) with 2-4 weeks intervals in an hospital or at home and willing to be treated with 1 infusion of Nanogam 50 mg/ml and 4 infusions of Nanogam 100 mg/ml at the hospital
- A stable clinical situation (no activity of any other disease; a stable immunoglobulin dose and frequency)
- Age 18 years or older
- The patient has signed the consent form

Exclusion criteria

- Known with allergic reactions against human plasma or plasma products
- Having an ongoing progressive disease, including HIV infection
- Pregnancy or lactation
- Known with insufficiency of coronary or cerebral circulation
- Having renal insufficiency (plasma creatinin > 115µmol/L)
- Having IgA deficiency and anti-IgA antibodies have been detected

Study design

Design

Study phase: 3

Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nanogam 100 mg/ml
Generic name:	human intravenous immunoglobuline 100 mg/ml
Product type:	Medicine
Brand name:	Nanogam 50 mg/ml
Generic name:	human intravenous immunoglobuline 50 mg/ml
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-05-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	25-07-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO

Date:	18-09-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	23-09-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2012-005727-32-NL
CCMO	NL43002.058.13