Treatment in patients with recurrent infections and IgG Subclass Deficiency, and/or Deficient Anti-Polysaccharide Antibody Response.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immunodeficiency syndromes
Study type	Interventional

Summary

ID

NL-OMON35384

Source
ToetsingOnline

Brief title
Treatment of deficient subclass and/or antipolysaccharide antibody response

Condition

- Immunodeficiency syndromes
- Respiratory tract infections

Synonym
antibody deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Plasmaproducten
Source(s) of monetary or material Support: zie G2

Intervention

Keyword: co-trimoxazol, IgG deficiency, Immunoglobulins, Intravenous, therapy

Outcome measures

Primary outcome

The primary clinical efficacy parameters are: the number, duration and type of infection (including use of antibiotics to treat infections), days of fever, hospital admissions and, if applicable, days absent from school or work due to infections.

Secondary outcome

Safety will be monitored by occurrence of adverse events, vital signs, and laboratory measurements.

Study description

Background summary

There is no consensus on the treatment of patients with recurrent infections and isolated IgG-subclass deficiency and/or selective antipolysaccharide antibody deficiency. Therefore, the Dutch Inter University Working Party intends to start a study in which the treatment with antibiotics will be compared with intravenous immunoglobulin therapy with respect to clinical outcome measures in both children and adults with this disorder.

Study objective

The primary objective of the study is to compare the efficacy of intravenous immunoglobulin product with the efficacy of antibiotic treatment in patients with recurrent respiratory infections and IgG-subclass deficiency and/or selective anti-polysaccharide antibody deficiency, and to define a treatment

protocol for this group of patients.
The secondary objective of the study is to compare the safety of intravenous immunoglobulin product with the safety of antibiotic treatment in this patient group.

Study design

All patients in this open, prospective multi-centre randomized cross-over study will be observed during a period of 2 x 12 months separated by a washout period of 3 months.

Intervention

In the study period that patients are treated with intravenous immunoglobulin, Nanogam will be administered in the following dosages:
• Adults: 600 mg/kg bodyweight every 3 weeks
• Children: 800 mg/kg bodyweight every 3 weeks

In the study period that patients are treated with antibiotics, Co-trimoxazol (trimethoprim/sulfamethoxazol) will be administered in the following dosages:
• Adults and children >=12 years or >=40 kg: 160 mg trimethoprim and 800 mg sulfamethoxazol once daily, every day of the week combined with 5 mg folic acid.
If not tolerated well: azitromycin 500 mg once daily, every other day, 3 days of the week.
• Children >=5-12: 4 mg trimethoprim and 20 mg sulfamethoxazol per kg bodyweight once daily, every day of the week (max160/800mg/day), combined with 5 mg folicacid.
If not well tolerated: azitromycin 10 mg per kg bodyweight once daily, every other day, 3 days a week (max 500 mg /day).

Study burden and risks

Nanogam and co-trimoxazol are both products with marketing authorization. From the experience with these products, no risks can be expected. The patient itself has no direct benefit by this clinical trial, but in the future, the patient itself and other patients will have the benefit of a treatment protocol for patients with these disorders.
The extra burden for the patient is limited, since a lot of the blood samplings and tests would also be performed without participation in the study because of their disease. At study entry, after 15 months (cross-over), and the end of the study (after 27 months) a physical examination and some tests (X-ray, optionally CT-scan, lung function,ENT examination) will be performed.
In total, 50-70 ml blood will be taken during the screening, and 30-50 ml during the subsequent visits. The patient will visit the clinic every 3 months (ten visits in 27 months). In case of infections, the visit frequency will be

increased, and cultures will be performed.
The patients have to enter all details on the use of Nanogam (out-patient clinic or home treatment) and co-trimoxazol (home treatment) in a patient*s diary. Before each Nanogam infusion a serum sample will be taken to analyze the IgG trough level.
The end of the study the patient will be asked to fill out a short questionnaire to evaluate both treatments.

Contacts

Public
Sanquin Plasmaproducten

Plesmanlaan 125
1066CX Amsterdam
NL
Scientific
Sanquin Plasmaproducten

Plesmanlaan 125
1066CX Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

IgG subclass deficiency and/or (selective) antipolysaccharide antibody deficiency, and at least 2 physician documented infections before the start of the current treatment or in the last 6 months for newly diagnosed patients.

Exclusion criteria

- Treatment with any other investigational drug within 7 days prior to study entry, or previous enrolment in this study
- Allergic reactions against human plasma/plasma products, or co-trimoxazol
- An ongoing progressive terminal disease
- Pregnancy or lactation
- Renal insufficiency (plasma creatinin > 115 µmol/L; or creatinin clearance <20 ml/min))
- An ongoing active disease causing general symptoms e.g. chronic active hepatitis or persistent enterovirus infection with ongoing systemic complaints
- Detectable anti-IgA antibodies
- Active SLE
- Glucose-6-phosphate hydrogenase deficiency

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2007
Enrollment:	60

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nanogam
Generic name:	human normal intravenous immunoglobulin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	not applicable
Generic name:	azitromycin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	not applicable
Generic name:	cotrimoxazole (trimethoprim/sulfamethoxazole)
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-01-2007
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	25-09-2007
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	26-02-2009
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	25-03-2010
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	

Date:	14-10-2010
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	EUCTR2006-005215-98-NL
CCMO	NL15291.058.06