A single centre, prospective, randomised, double-blind, placebo controlled, sequential, dose-escalating phase I study to assess the safety and tolerability of intravenously infused single doses of OPN-305 in healthy subjects.

Published: 11-04-2011
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Primary : - to assess the safety and tolerability of a single ascending intravenous iv infused doses of OPN-305 in healthy subjects- determination of dose and infusion time for Phase II studiesSecondary : - to determine the pharmacokinetic profile...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON38332

Source
ToetsingOnline

Brief title
OPN-305 SAD study

Condition

- Renal and urinary tract therapeutic procedures

Synonym
inflammatory reactions, rejections

Research involving

Human

Sponsors and support

Primary sponsor: Opsona Therapeutics Ltd.
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: Healthy volunteers, OPN-305, SAD

Outcome measures

Primary outcome

Pharmacodynamics: antibodies concentrations, inflammatory cytokine levels, PD markers

Pharmacokinetics: plasma OPN-305 concentrations, pharmacokinetic parameters

Safety: adverse events, vital signs, ECG-parameters, laboratory parameters, physical examination

Secondary outcome

NA

Study description

Background summary

As this study is the first study in humans, to date adverse effects in man have not been reported. In previous studies with mice and monkeys with dosing once weekly at dosages up to 100 mg/kg/week no adverse effects were observed. With the doses used in this study no serious adverse effects are expected. However, the possibility that any adverse effects could occur cannot be entirely excluded. All potential drugs cause to some extent adverse events. One adverse event that may occur is an increased susceptibility for infections. This is also the main reason why you will be tested for tuberculosis, as this disease can become active if you are positive without knowing this. However, you should take into account that some risks are still unknown at this moment.

Study objective

Primary :
- to assess the safety and tolerability of a single ascending intravenous iv infused doses of OPN-305 in healthy subjects
- determination of dose and infusion time for Phase II studies

Secondary :
- to determine the pharmacokinetic profile OPN-305 after a single intravenous injection in healthy subjects
- to determine the immunogenicity of OPN-305 after a single intravenous injection in healthy subjects
- to confirm that there are no unexpected changes in plasma inflammatory cytokines (e.g. TNF*, IL-1*, IL-6 and IFN-*)
- to evaluate the effect of OPN-305 on PD parameters

Study design

a randomized, double-blind, placebo-controlled, single-ascending dose study in three cohorts of six healthy male subjects and two cohorts of eight healthy male subjects receiving a single iv infusion of OPN-305 or placebo, the first cohort is staggered in such a manner that two subjects (one verum and one placebo) are dosed, at least, twenty-four hours prior to the next two subjects and, at least, twenty-four hours later the remaining two subjects, the other cohorts are staggered in such a manner that two subjects (one verum and one placebo) are dosed, at least, twenty-four hours prior to the remaining subjects

Intervention

Cohort 1: a single 2-hour iv infusion of 0.5 mg/kg OPN-305 or placebo in the fasted state
Cohort 2: a single 2-hour iv infusion of 1.5 mg/kg OPN-305 or placebo in the fasted state
Cohort 3: a single 2-hour iv infusion of 5 mg/kg OPN-305 or placebo in the fasted state
Cohort 4: a single 1-hour iv infusion of 5 mg/kg OPN-305 or placebo in the fasted state
Cohort 5: a single 1-hour iv infusion of 10 mg/kg OPN-305 or placebo in the fasted state

Study burden and risks

Light bleeding and/or an infection may occur due to the use of the canula.

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

Healthy male volunteers; 18 - 60 years; BMI 18.0 - 28.9 kg/m2; moderate or non-smoker.

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 90 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-06-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	11-04-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-04-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-08-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	09-08-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2011-000963-29-NL
CCMO	NL36426.056.11