Follow-up Protocol to the Double-Blind Parts A and B of the Phase II Opsona Study OPN305-102 (A Three-Part, Multi-Centre, Randomised, Double-Blind, Placebo-Controlled, Parallel-Group, Sequential Adaptive, Phase II Study to Evaluate the Safety, Tolerability and Efficacy of OPN-305, a Humanised Monoclonal Antibody that Blocks Toll-Like Receptor 2, in Renal Transplant Patients at High Risk of Delayed Graft Function)

Published: 21-03-2014
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To assess out to one-year the clinical status of patients who completed the double-blind part B of the 6-month study period in the Opsona phase II protocol (OPN305-102) by recording the following:• Incidence of biopsy-proven allograft rejection or...

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

Summary

ID

NL-OMON45118

Source
ToetsingOnline

Brief title
FU Protocol to the Double-Blind Parts A+B of the Phase II Study OPN305-102

Condition

- Renal and urinary tract therapeutic procedures

Synonym
prevent kidney graft dysfunction following cadaveric renal transplantation organ

Research involving
Human

Sponsors and support

Primary sponsor: Opsona Therapeutics Ltd
Source(s) of monetary or material Support: industry

Intervention

Keyword: Delayed Graft Function, Humanised IgG4 monoclonal antibody, Renal Transplant

Outcome measures

Primary outcome

• Incidence of biopsy-proven allograft rejection or graft loss

• Initiation and frequency of dialysis or other renal replacement therapy (RRT)

• Estimated GFR at the end of the 6-month follow-up period based on a

determination of serum creatinine, Cystatin C and symmetrical dimethylarfinine

(SDMA) by the central laboratory

• Incidence and type of serious adverse events (SAEs)

• The occurrence of infections by type and actual organism

• The incidence of hospitalisations

Secondary outcome

not applicable

Study description

Background summary

OPN-305 is a humanised IgG4 monoclonal antibody (MAb) against TLR2 that has orphan medicinal product designation from the European Medicines Agency (EMA) for prevention of Delayed Graft Function (DGF) following solid organ transplantation. A similar designation has been granted by the Food & Drug Administration in the USA in December 2011.

A multi-centre, randomised, double-blind, placebo-controlled, parallel-group, sequential adaptive, phase II study to evaluate the safety, tolerability and efficacy of OPN-305 in renal transplant patients at high risk of delayed graft function (protocol OPN305-102) was initiated in November 2012. That study includes safety and efficacy procedures and evaluations up to six months after administration of OPN-305.

The current protocol (version 3) is a follow-up study, for patients from Part B of study OPN305-102 who consent to participate out to 12 months following OPN-305 or placebo administration, of the clinical status and graft function of patients who participated in and completed the 6-month double-blind part B of the phase II study described above.

Study objective

To assess out to one-year the clinical status of patients who completed the double-blind part B of the 6-month study period in the Opsona phase II protocol (OPN305-102) by recording the following:
• Incidence of biopsy-proven allograft rejection or graft loss
• Initiation and frequency of dialysis or other renal replacement therapy (RRT)
• Estimated GFR at the end of the 6-month follow-up period based on a determination of serum creatinine, Cystatin C and SDMA by the Central laboratory
• Incidence and type of serious adverse events (SAEs)
• The occurrence of infections by type and actual organism
• The incidence of hospitalisations

Study design

All patients entered in this follow-up study will attend a 3-month and 6-month study visit corresponding to 9 and 12 months after their study-drug administration in the initial phase II trial (OPN305-102). To indicate this continuity the study visits will be described in this follow-up protocol as being at 9 and 12 months following administration of OPN-305/placebo. Patients will be informed that they have the right to withdraw from the study at any time, without prejudice to their medical care, and are not obliged to state

their reasons. Any withdrawals must be fully documented and should be followed up by the Investigator to complete an end-of-study evaluation if possible.

Schedule Of Assessments And Procedures: It is expected that patients will be asked to give a written informed consent to participate in the follow-up study at the completion (6-month) visit in the phase II study (OPN305-102) but a window of 1 week is permitted to allow for any unforeseen circumstance(s).

Nine-Month Post-Treatment Follow-up Study Visit: If no routine or for-cause visit is scheduled within 1 month either side of the 9-month post-treatment visit then a study-specific visit must be scheduled for the patient to come to the study site.

Twelve-Month Post-Treatment Follow-up Study Visit: If no routine or for-cause visit is scheduled within 1 month either side of the 12-month post-treatment visit then a study-specific visit must be scheduled for the patient to come to the study site.

Other Visit(s): It is anticipated that patients will return to the study sites for routine follow up visits and for cause. In the event such a visit occurs within a month either side of the 9-month or 12-month post-treatment visit this will be considered as the protocol visit for timing purposes. Where these visits occur outside of the time window permitted for the 9- or 12-month visit then the relevant CRFs will be completed for each visit.

Withdrawal: If a patient withdraws from the study the Investigator will try to complete an end-of-study evaluation if the patient agrees.

Study burden and risks

not applicable

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

• Completion of the double-blind part B of the 6-month study visit in the phase II trial (OPN305-102)
• Provide written informed consent for the follow-up protocol.

Exclusion criteria

• Refusal to give written informed consent
• Withdrawn from OPN305-102 prior to the 6 month final visit
• Plan to be included into another interventional investigational study

Study design

Design

Study phase:	2
Study type:	Observational invasive
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):	06-06-2014
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NA
Generic name:	Humanised IgG4 Monoclonal Antibody Against Toll-like receptor 2 (sub33114)

Ethics review

Approved WMO Date:	21-03-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-06-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	08-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2012-005767-27-NL
CCMO	NL47258.042.14