The clinical importance of the neonatal Fc receptor in RPE.

Published: 18-09-2008
Last updated: 06-05-2024

1) To demonstrate that the FcRn functions as a transporter and protector for vitreous IgG and monoclonals (Avastin, Lucentis) and show that monoclonal therapeutic antibodies are transported over the RPE via the FcRn. 2) To investigate if...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON32041

Source
ToetsingOnline

Brief title
FcRn in the RPE.

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
age related macular degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis Prof. Dr. H.J. Flieringa (SWOO).

Intervention

Keyword: Age related macular degeneration, FcRn gene, Retinal pigment epithelium

Outcome measures

Primary outcome

Confirmation of the role of FcRn in metabolism and transport of vitreous IgG

and monoclonals (Avastin, Lucentis), frequency of FcRn mutations and

polymorphisms.

Secondary outcome

NA

Study description

Background summary

IgG levels in the vitreous are used to diagnose ocular infections (Goldmann-Witmer) and recently anti-VEGFs (Avastin, Lucentis) have been introduced to treat neovascular age related macular degeneration (ARMD). In the near future other immunoglobulin based biologicals will be injected in the eye. Monoclonal anti-TNF antibodies such as Remicade and Humira are promising candidates for local administration and also cytotoxic monoclonals like rituximab - for treating ocular lymphomas - are to be injected locally. However, knowledge about metabolism of IgG in the eye is scarce. Investigation of the metabolism and transport mechanisms of these antibodies is therefore warranted.
Mutations or polymorphisms of the FcRn gene may indicate a predisposition for ARMD. The fact that IgG is found in drusen and in retinal pigment epithelial (RPE) cells adjacent to drusen indicates a possible role for IgG and therefore the neonatal Fc receptor (FcRn) in the development of ARMD.

Study objective

1) To demonstrate that the FcRn functions as a transporter and protector for vitreous IgG and monoclonals (Avastin, Lucentis) and show that monoclonal therapeutic antibodies are transported over the RPE via the FcRn. 2) To investigate if polymorphisms or mutations in the FcRn gene or promoter are

related to ARMD.

Study design

1) laboratory research and 2) observational cohort study.

Study burden and risks

Participants do not benefit from this study. Risks are negligible.

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
NL
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18 years
- Informed consent
- Age related macular degeneration (ARMD group) or no ARMD (control group)

Exclusion criteria

None

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-06-2009
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	18-09-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL23735.078.08