Destructive inflammatory reaction after an autologous retinal pigment epithelium and choroid transplantation

Published: 28-05-2020
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Development of a laboratory assay

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

Summary

ID

NL-OMON49580

Source
ToetsingOnline

Brief title
Rejection-like reaction RPE-choroid graft

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Rejection-like reaction RPE-choroid graft

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Combined Opthalmic Research Rotterdam

Intervention

Keyword: autologous graft, rejection reaction, RPE-choroid

Outcome measures

Primary outcome

The presence or absence of anti-RPE and anti-choroid auto-antibodies

Secondary outcome

HLA haplotype

Genotype analyse om polymorphismen gerelateerd aan immunologische mechanismen

aan te tonen. Complement activatie

Study description

Background summary

5 patients developed a rejection-like reaction after an autologous transplantation of retinal pigment epithelium (RPE) and choroid for exudative age-related macular degeneration (AMD). Surgically damaged tissue may have elicited an inflammatory destructive reaction, either auto-immune or aspecific.

Study objective

Development of a laboratory assay

Study design

Case-control study

Study burden and risks

Participants do not benefit, risks are negligible, burden is low.

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

Age * 18 years
Informed consent

Exclusion criteria

A history of diabetic retinopathy, uveitis, or systemic auto-immune disease

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:	Recruitment stopped
Start date (anticipated):	26-06-2020
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	28-05-2020
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	NL72704.078.20