The Baerveldt Implant. Corneal endothelial changes and tube position.

Published: 19-12-2014
Last updated: 15-05-2024

To determine the effect of tube position in the anterior chamber on the corneal endothelium.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON41928

Source
ToetsingOnline

Brief title
Baerveldt tube & endothelium

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Baerveldt implant, Endothelial cell density, Tube distance

Outcome measures

Primary outcome

Correlation between endothelial cell counts and tube position.

Secondary outcome

Pachymetry.

Cell morphology.

Stromal changes.

Tube length.

Corneal decompensation.

Study description

Background summary

Implantation of the Baerveldt glaucoma drainage device is a common procedure for glaucoma management. A silicon tube is then put in the anterior chamber of the eye. Postoperative corneal endothelial changes, notably a reduction in endothelial cell count are quite common, sometimes leading to corneal decompensation requiring corneal transplant surgery. It is unclear to what extent tube position in the anterior chamber plays a role in the pathogenesis of the corneal changes.

Study objective

To determine the effect of tube position in the anterior chamber on the corneal endothelium.

Study design

Prospective observational.

Study burden and risks

Participation does not involve any additional risk. Burden is limited to the additional time needed for extra measurements. These assessments will be

performed at the time of regular visits and take about one hour extra time (5X).

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 18-80 years.
Informed consent.
Primary open-angle glaucoma, pseudoexfoliative glaucoma, pigmentary glaucoma or normal tension glaucoma.

Exclusion criteria

History of corneal diseases (e.g. Fuchs* endothelial dystrophy, HSV keratitis).
Cataract surgery less than 12 months before.
History of ocular comorbidity.
Functionally monocular patients.
Need for glaucoma surgery combined with other ocular procedures or an anticipated need for additional ocular surgery.
Best corrected visual acuity less than 0.1.
Study eye received Baerveldt implant before.
Fellow eye already included in this study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	19-11-2015
Application type:	Amendment
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

ID: 29065
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51175.078.14
OMON	NL-OMON29065