The Baerveldt Implant. Corneal endothelial changes and tube position.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29065

Source
Nationaal Trial Register

Health condition

Glaucoma

Sponsors and support

Primary sponsor: Het Oogziekenhuis Rotterdam (OZR)
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Correlation between endothelial cell counts and tube position.

Secondary outcome

- Pachymetry.

- Cell morphology (polymegathism, pleomorphism).
- Stromal changes.
- Tube length.
- Tube bevel.
- Corneal decompensation.

Study description

Background summary

Rationale: 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.
Objective: To determine the effect of tube position in the anterior chamber on the corneal endothelium.
Study design: Prospective observational.
Study population: Glaucoma patients scheduled for a Baerveldt implant.
Main study parameter: Correlation between endothelial cell counts and tube position.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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).

Study objective

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

Study design

pre-op, 1d,2w,6w,12m,24m

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

- Age 18-75 years.
- Informed consent.
- Primary open-angle glaucoma, pseudoexfoliative glaucoma, or pigmentary glaucoma.

Exclusion criteria

- History of intraocular surgery (i.e. strabismus surgery, tenon’s capsule or conjunctiva surgery, cataract surgery, cyclodestructive procedures etc.).
- History of ocular comorbidity (e.g. active uveitis, proliferative diabetic retinopathy).
- Pregnant or nursing women.
- Functionally monocular patients.
- Need for glaucoma surgery combined with other ocular procedures (i.e. cataract surgery, keratoplasty, or retinal surgery) or an anticipated need for additional ocular surgery.
- Best corrected visual acuity less than 0.1.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	06-01-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41928
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4823
NTR-old	NTR4946
CCMO	NL51175.078.14
OMON	NL-OMON41928

Study results

Summary results

van Kleij J, Islamaj E, de Waard PWT, Vermeer KA, Lemij HG. The long-term postoperative effect of the Baerveldt glaucoma drainage device and trabeculectomy on the corneal endothelium. Acta Ophthalmol. 2020; 98(Suppl. S264): 20.
[Abstract]

van Kleij JM, Islamaj E, Vermeer KA, Lemij HG, de Waard PWT. The long-term postoperative effect of the Baerveldt glaucoma drainage device and of a trabeculectomy on the corneal endothelium. Acta Ophthalmol. 2022; 100(2): 212-217.
PMID: 33629525