Comparing the Baerveldt and Paul glaucoma drainage devices and their effects on the corneal endothelium

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To detemine whether the Paul tube induces less damage to the corneal endothelium than the Baerveldt GDD.

Ethical review	Approved WMO
Status	Pending
Health condition type	Glaucoma and ocular hypertension
Study type	Interventional

Summary

ID

NL-OMON51284

Source
ToetsingOnline

Brief title
Baerveldt vs Paul

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: cornea, endothelial cell density, glaucoma drainage device

Outcome measures

Primary outcome

Endothelial cell density and tube position at 24 months.

Secondary outcome

Intraocular pressure

Motility

Flare

Study description

Background summary

The Baerveldt glaucoma drainage device (GDD) successfully reduces introacular pressure but also involves a risk of corneal endothelial deterioration. Supposedly, the tip of a GDD tube with a thinner diameter, such as the Paul implant, will remain at a larger distance from the cornea and, thereby, cause less damage.

Study objective

To detemine whether the Paul tube induces less damage to the corneal endothelium than the Baerveldt GDD.

Study design

Randomized clinical trial.

Intervention

Either a Baerveldt or a Paul GDD implant.

Study burden and risks

The Paul GDD may have a less harmful effect on corneal endothelium. Otherwise, both GDDs will probably have a similar risk/benefit profile. The risks of study-related assessments are negligible, burden is low, extra time is about 5 x 1.5 h (total 7.5 h).

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 - 75 years.
Caucasian ethnicity (to facilitate comparison of results with those of earlier work).
Primary open-angle glaucoma, pseudoexfoliative glaucoma, or pigmentary glaucoma.

Exclusion criteria

Normal pressure glaucoma.
History of ocular surgery (e.g. intraocular or strabismus surgery, tenon*s capsule or conjunctiva surgery, cyclodestructive procedures etc).
History of ocular comorbidity (e.g. active uveitis, proliferative diabetic retinopathy).
Pseudophakia.
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.
Narrow anterior chamber angle.
Best corrected visual acuity less than 0.1.
Severe blepharitis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2022
Enrollment:	160
Type:	Anticipated

Medical products/devices used

Generic name:	Baerveldt glaucoma implant versus Paul glaucoma implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-04-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-06-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL80518.078.22