Endothelial cell loss in pseudophakic patients receiving a Paul glaucoma drainage device with its tube inserted in the anterior versus posterior chamber: a randomized controlled trial

Published: 11-08-2022
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Primary: to determine the loss of corneal endothelial cells after implantation of a Paul GDD with its tube either anterior or posterior of the iris. Secondary: to compare efficacy and safety of both procedures.

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

Summary

ID

NL-OMON51545

Source
ToetsingOnline

Brief title
Paul GDD-tube Positioning

Condition

- Glaucoma and ocular hypertension

Synonym
corneal endothelium

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: ZonMW;Topspecialistische Zorg & Onderzoek (TZO)

Intervention

Keyword: Corneal endothelium, Glaucoma, Paul drainage device, Tube position

Outcome measures

Primary outcome

Endothelial cell loss of the cornea.

Secondary outcome

Intraocular pressure.

Location of the tube.

Adverse events.

Study description

Background summary

Glaucoma is a group of diseases characterized by progressive neuropathy of the optic nerve associated with visual field loss. Current glaucoma management aims to preserve visual function throughout life by reducing the intraocular pressure. This can be achieved by medical therapy or by surgical procedures such as implantation of a glaucoma drainage device (GDD). Conventionally, the tube of such a device is positioned in the anterior chamber (AC). Unfortunately, the presence of the tube in the AC may have a significant negative impact on the number of endothelial cells of the cornea and may even lead to corneal decompensation. Alternatively, the tube can be positioned in the posterior chamber (i.e. behind the iris). In this study, both procedures will be compared.

Study objective

Primary: to determine the loss of corneal endothelial cells after implantation of a Paul GDD with its tube either anterior or posterior of the iris.

Secondary: to compare efficacy and safety of both procedures.

Study design

Prospective, randomised, treatment controlled clinical trial.

Intervention

Implantation of a Paul GDD with its tube anterior/posterior of the iris.

Study burden and risks

At present potential benefits and drawbacks of positioning the Paul tube behind the iris are insufficiently known, successful positioning of the tube may require slightly more surgery time and the risk of hyphaema may be higher. It is expected, that in the long run damage to the corneal endothelium is less. Risks of study-related assessments are negligible, burden is low, extra time is about 35+15+35+35 minutes (total 2h).

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

Pseudophakic.
Diagnosed with open angle glaucoma, pseudoexfoliation glaucoma, pigment dispersion glaucoma or angle-closure glaucoma with a sufficiently deep AC.
Endothelial image at baseline of fair or good quality.

Exclusion criteria

Iridocorneal endothelial syndrome of posterior polymorphous dystrophy.
History of penetrating trauma.
History of intraocular surgery other than uncomplicated cataract surgery.
Corneal disease.
Pregnant and lactating women.

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:	Recruiting
Start date (anticipated):	20-10-2022

Enrollment:	200
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	11-08-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-11-2022
Application type:	Amendment
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	NL81305.078.22