Primary Baerveldt glaucoma implant versus trabeculectomy study.

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Demonstrate that compared to trabeculectomy, at 12 months follow-up:- a Baerveldt implant is not inferior with respect to IOP and- a Baerveldt implant is superior with respect to failure.

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

Summary

ID

NL-OMON40102

Source
ToetsingOnline

Brief title
Primary Baerveldt implant

Condition

- Glaucoma and ocular hypertension

Synonym
glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis - Prof. Dr. H. J. Flieringa (SWOO)

Intervention

Keyword: Baerveldt implant, Glaucoma, Intraocular pressure, Trabeculectomy

Outcome measures

Primary outcome

- IOP at 12 montns.

- Failure rate at 12 months.

Secondary outcome

- IOP development during follow-up.

- Failure rate during follow-up.

- Need for supplemental medical therapy.

- Best corrected visual acuity (ETDRS).

- Visual field (HFA 24-2; SITA).

- Motility changes.

- Laser flare count.

- Incidence and type of complications.

Study description

Background summary

Presently, the only proven treatment of glaucoma is a reduction of intraocular pressure (IOP). Depending on severity, treatment options are medication, laser treatment or trabeculectomy. The latter is considered when other treatment modalities are ineffective. The results of a recent study suggest that a drainage device, such as the Baerveldt implant, may be a good alternative for trabeculectomy.

Study objective

Demonstrate that compared to trabeculectomy, at 12 months follow-up:

- a Baerveldt implant is not inferior with respect to IOP and
- a Baerveldt implant is superior with respect to failure.

Study design

This is a prospective, randomized, parallel group, open-label, monocenter study of patients with glaucoma.

Intervention

Baerveldt implant vs. trabeculectomy.

Study burden and risks

Participants are scheduled for trabeculectomy. Visit schedule will be as for standard surgery. The control group will neither benefit from participating in this study, nor be at a greater risk than usual. It is expected that a Baerveldt implant is not inferior to trabeculectomy. The failure rate may be lower. It is conceivable, therefore, that the Baerveldt group may benefit from participating in this study, although the need for supplemental medical therapy may be higher. Study-related extra time for complete follow-up of 5 years will be 3.5 hours in total.

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.
- Informed consent.
- Caucasian.
- Expected to complete follow-up of 5 years.
- Primary open-angle glaucoma, pseudoexfoliative glaucoma or pigmentary glaucoma.
- Indication for IOP lowering surgery.

Exclusion criteria

- IOP exacerbating glaucoma by further delay of pressure reduction.
- Normal pressure glaucoma.
- History of ocular surgery.
- History of ocular comorbidity.
- Pregnant or nursing women.
- Functionally monocular patients.
- Need for glaucoma surgery combined with other ocular procedures or aniticipated need for additional ocular surgery.
- Narrow anterior chamber angle.
- Best corrected visual acuity less than 0.1.
- Severe blepharitis.
- History of strabismus.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2008
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	Baerveldt implant type: BG-101-350
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-11-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	10-04-2014
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	NL19835.078.07