# Primary Baerveldt glaucoma implant versus trabeculectomy study.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27793

**Source**
Nationaal Trial Register

**Brief title**
N/A

**Health condition**

Glaucoma.

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam
Schiedamsevest 180
3011 BH Rotterdam
**Source(s) of monetary or material Support:** Stichting Wetenschappelijk Onderzoek het Oogziekenhuis

### Intervention

### Outcome measures

**Primary outcome**

1. Intraocular pressure at 12 months;

2. Failure rate at 12 months.

**Secondary outcome**

1. IOP development during follow-up;

2. Failure rate during follow-up;

3. Need for supplemental medical therapy;

4. Best corrected visual acuity (ETDRS);

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

6. Motility changes;

7. Laser flare count;

8. Incidence and type of complications.

# Study description

**Background summary**

Rationale:

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

1. a Baerveldt implant is not inferior with respect to IOP and;

2. 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.

Study population:

Glaucoma patients scheduled for trabeculectomy.

Intervention:

Baerveldt implant vs. trabeculectomy.

Main study parameters/endpoints:

IOP and failure rate at 12 montns.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

**Study objective**

A Baerveldt implant is a good alternative for trabeculectomy.

**Study design**

1. pre-op;

2. 1d;

3. 2w;

4. 6w;

5. 3m;

6. 6m;

7. 1y;

8. 2y;

9. 3y;

10. 4y;

11. 5y.

**Intervention**

Baerveldt implant vs. trabeculectomy.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Age 18-75 years;

2. Informed consent;

3. Caucasian;

4. Expected to complete follow-up of 5 years;

5. Primary open-angle glaucoma, pseudoexfoliative glaucoma or pigmentary glaucoma;

6. Indication for IOP lowering surgery.

### Exclusion criteria

1. IOP exacerbating glaucoma by further delay of pressure reduction.
(Because implant remains closed until 6 weeks post-op, assigning such a patient to the Baerveldt group would be unethical).

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2008 |
| Enrollment: | 120 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 27-11-2007 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL1108 |
| NTR-old | NTR1142 |
| Other | Oogziekenhuis RotterdamSchiedamsevest 1803011 BH Rotterdam : OZR-2007-05 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**

Islamaj E, Wubbels RJ, de Waard PWT. Primary Baerveldt versus trabeculectomey study after one year follow-up. Acta Ophthalmol. 2018; 96(6): e740-e746.
PMID: 30022618
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Islamaj E, Jordaan-Kuip CP, Vermeer KA, Lemij HG, de Waard PWT. Motility Changes and Diplopia After Baerveldt Glaucoma Drainage Device Implantation or After Trabeculectomy. Trans Vis Sci Tech. 2018; 7(5): 7.
PMID: 30221073
<br>
Islamaj E, Wubbels RJ, de Waard PWT. Primary Baerveldt versus Trabeculectomy study after 5 years of follow-up. Acta Ophthalmol. 2020; 98(4): 400-407.
PMID: 31729825
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