

The Baerveldt Implant. Is postoperative ocular motility improved when conventional securing to the sclera is omitted?

No registrations found.

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

Summary

ID

NL-OMON26224

Source

Nationaal Trial Register

Brief title

Baerveldt implant & Ocular motility.

Health condition

Glaucoma.

Sponsors and support

Primary sponsor: Het Oogziekenhuis Rotterdam.

Source(s) of monetary or material Support: ZonMW.

Intervention

Outcome measures

Primary outcome

Incidence of impaired ocular motility with or without diplopia at 3 months.

Secondary outcome

- Orthoptic parameters.
- Intraocular pressure.
- Failure rate at 12 months.
- Visual acuity.

Study description

Background summary

Between surgeons, techniques may differ in various degrees and for sundry reasons. One such difference is the suturing or no suturing of the plate of a Baerveldt implant to the sclera.

The objective is to monitor the effect of the free plate technique in Baerveldt implant surgery on the postoperative eye motility.

(This study is related to NTR1142; results will be compared.)

Study objective

The free plate technique in Baerveldt implant surgery reduces postoperative eye motility disturbance.

Study design

Pre-op, 1d, 2w, 6w, 3, 6, 12m.

Intervention

Baerveldt Implant (free plate).

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- Normal pressure glaucoma.
- History of ocular surgery.
- 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 or an anticipated 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:	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:	90
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	30-09-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44687

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4674
NTR-old	NTR4826
CCMO	NL50037.078.14
OMON	NL-OMON44687

Study results

Summary results

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, <https://doi.org/10.1167/tvst.7.5.7>.