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

Published: 30-09-2014
Last updated: 15-05-2024

To monitor the effect of the free plate technique in Baerveldt implant surgery on the postoperative eye motility.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON44687

Source
ToetsingOnline

Brief title
Baerveldt implant & ocular motility.

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: Baerveldt implant, Glaucoma, Ocular motility

Outcome measures

Primary outcome

Incidence of impaired ocular motility at 3 months.

Secondary outcome

IOP, BCVA etc.(see protocol p. 7).

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.

Study objective

To monitor the effect of the free plate technique in Baerveldt implant surgery on the postoperative eye motility.

Study design

Prospective observational.

Study burden and risks

Participation does not involve any additional risk. Study-related extra measurements will be performed at the time of regular control visits. Total extra time required is 8 hours. Duration of this study is 12 months.

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.
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).
Functionally monocular patients.
Need for glaucoma surgery combined with other ocular procedures.
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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2014
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	30-09-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	16-05-2017
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

ID: 26224
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50037.078.14
OMON	NL-OMON26224