Measurement of retinal blood flow in glaucoma patients before and after Baerveldt Shunt Implantation

Published: 01-02-2018
Last updated: 12-04-2024

The aim of this study is to explore the capability of the RFI to measure short and long term changes in retinal blood flow velocity and oximetry maps before and after a BGI and to compare these results with OCTA measurements.

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

Summary

ID

NL-OMON46550

Source
ToetsingOnline

Brief title
Retinal blood flow & BGI

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 (SWOO)

Intervention

Keyword: Baerveldt, Glaucoma, Retinal blood flow

Outcome measures

Primary outcome

Blood flow at baseline and 3 months after BGI.

Secondary outcome

OCTA measurements

IOP

Study description

Background summary

There is increasing evidence that ocular blood flow impairment contributes to the progression of glaucomatous damage. One of the most frequent surgical treatments for open angle glaucoma is the Baerveldt Glaucoma Implant (BGI). It is conjectured that both the presence of the device (by its mechanical effect on the eye) together with the reduction of intraocular pressure may affect retinal hemodynamics. The retinal function imager (RFI) allows the measurement of retinal blood flow velocity and oximetry. With this device, it will be attempted to determine short and long term changes in the microvascular condition of patients who receive a BGI. These measurements will be compared to the results that are obtained with optical coherence tomography angiography (OCTA).

Study objective

The aim of this study is to explore the capability of the RFI to measure short and long term changes in retinal blood flow velocity and oximetry maps before and after a BGI and to compare these results with OCTA measurements.

Study design

Prospective, observational, single center study.

Study burden and risks

Risks are negligible. Patients do not benefit from participation. Study visits will be combined with regular clinical visits. Extra study related time is approximately 2 X 1.5 hours (total 3 hours).

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
Rotterdam 3011 BH
NL
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
Rotterdam 3011 BH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosed high IOP (IOP > 23 mm Hg and <= 40 mm Hg).
18 to 75 years of age.
BCVA of 0.3 or better
Refractive error between -5 and +5 D.
Clear media.

Exclusion criteria

History of atrial fibrillation, atrial flutter, or cardiac pacemaker.
Alcohol, smoking and coffee are not allowed from at least 8 hours before measurements.
Previous intraocular surgery, except uncomplicated cataract extraction > 12 months ago
Evidence of an ocular disease, other than glaucoma or cataract that might interfere with the measurements.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2018
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	01-02-2018
Application type:	First submission
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	NL64383.078.17