Effectiveness and cost-effectiveness of MicroShunt (MS) implantation versus standard trabeculectomy (TE)

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The objective of this project is to aid in deciding on the use of the MicroShunt in glaucoma surgery by assessing its efficacy and cost-effectiveness in patients with primary open-angle glaucoma (POAG), pigment dispersion syndrome or ocular…

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

Summary

ID

NL-OMON52755

Source
ToetsingOnline

Brief title
(Cost-)effectiveness of MS vs. TE (SIGHT)

Condition

- Glaucoma and ocular hypertension
- Eye therapeutic procedures

Synonym
glaucoma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: - Cost-effectiveness, - InnFocus MicroShunt (MS), - PRESERFLO MicroShunt, - Trabeculectomy (TE)

Outcome measures

Primary outcome

The primary outcome measure is IOP after 12 months of follow-up.

Secondary outcome

Secondary outcome measures are best corrected visual acuity, glaucoma

medications, safety (complications and surgical interventions), visual fields,

vision-related quality of life and generic health-related quality of life, and

costs, cost-effectiveness and budget impact.

Study description

Background summary

The standard surgical treatment for glaucoma is trabeculectomy. The MicroShunt (MS) is a new, minimally invasive method which has been suggested to result in similar IOP lowering, but with faster visual recovery and less complications and postoperative interventions. However, this is based on limited evidence, underscoring the need for a randomized controlled trial (RCT).

Study objective

The objective of this project is to aid in deciding on the use of the MicroShunt in glaucoma surgery by assessing its efficacy and cost-effectiveness in patients with primary open-angle glaucoma (POAG), pigment dispersion syndrome or ocular hypertension compared to trabeculectomy (TE).

Study design

Multi-center, randomized, single blind, non-inferiority, interventional clinical trial, involving 9 medical centers in the Netherlands.

Intervention

MicroShunt implantation augmented mitomycin C versus a standard trabeculectomy augmented with mitomycin C.

Study burden and risks

Potential benefits of participating in this study (for patients allocated to the MicroShunt implantation) are a shorter surgery duration, and a faster recovery (e.g. of the visual acuity). Potential risks associated with participation in this study are the potential risks of a standard trabeculectomy. The most important complications are: hyphema, inflammation of the anterior chamber, wound-/or bleb-leakage, shallow anterior chamber, hypotony and hypotony maculopathy, suprachoroidal hemorrhage or choroidal effusion syndrome, and endophthalmitis. There is also an increased risk of developing cataract after the surgery. The risk of one of these complications is expected to be either similar for both surgeries or lower for the MicroShunt implantation. However this is based on the little evidence, that is currently available. Compared to usual care, the extra burden for all patients participating in this study is filling in questionnaires five times during the study, which will take 20 to 30 minutes per time.

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

Adult Caucasian patients aged between 18 and 80 years old with uncontrolled open-angle glaucoma (pigment dispersion syndrome and pseudo exfoliation syndrome allowed) or ocular hypertension on (maximum tolerated) medical therapy and/or progression with an indication for primary glaucoma surgery (trabeculectomy) are suitable for inclusion.
Open-angle glaucoma is defined as an open drainage angle (>= Shaffer grade II, trabecular meshwork visible in 360 degrees).

Exclusion criteria

1. Patient unwilling or unable to give informed consent, unwilling to accept randomization or inability to complete follow-up (e.g. hospital visits) or comply with study procedures
2. Secondary glaucoma (e.g. iris neovascularization, rubeosis iridis, trauma, epithelial or fibrous down growth, iridocorneal endothelial syndrome).
3. Previous incisional surgery of the subject eye. Previous uncomplicated clear corneal cataract surgery is allowed >6 months prior to the surgery.
4. Poor vision in either the study or fellow eye. Poor vision is defined as a corrected vis-ual acuity <0.5, with the exception of pre-existent amblyopia of the study eye (<0.2), and/or a mean deviation worse than -20dB on the visual field.
5. Any ocular comorbidities that could affect the visual field. (e.g. diabetic retinopathy, proliferative retinopathy, aphakia, degenerative visual disorder not associated with glaucoma)
6. Chronic or recurrent uveitis.
7. Need for glaucoma surgery combined with other ocular procedures or anticipated need for additional ocular surgery.
8. Anatomical factors that increase the risk of complicated surgery (due to previous trauma, anatomical abnormalities, anterior synechiae or previous cyclodestructive procedure).
9. Conditions that increase the risk of endophthalmitis.

- Current ocular, adnexal or periocular infections (e.g., untreated severe blepha-ritis)
- Immune compromised patients including the use of topical or systemic steroids for an indication other than the surgery within 3 months of the procedure (this would not include the use of inhaled or dermatologic steroids), chemotherapy within 6 months of the procedure.
- Iodine allergy
- Unwilling to temporarily discontinue contact lens after surgery
10. Contraindication or allergy to mitomycin C.
11. Any contraindication to tube placement (e.g. shallow anterior chamber, insufficient endothelial cell density).
12. Use of oral hypotensive glaucoma medications for treatment of the fellow eye.
13. Prior ocular laser treatment within 3 months of the surgery, increasing the risk of inflammation in the eye.
14. Corneal thickness <450um or >620microns.
15. Conditions associated with elevated episcleral venous pressure such as active thyroid orbitopathy.
16. Among patients in whom both eyes are eligible only the first eye is undergoing surgical treatment is enrolled in the study.
17. Participation in another clinical study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-02-2020
Enrollment:	124
Type:	Actual

Medical products/devices used

Generic name:	PRESERFLO MicroShunt implantation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-11-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-01-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-11-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-05-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 20100
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT03931564
CCMO	NL68964.068.19
OMON	NL-OMON20100