(Cost-)effectiveness of MicroShunt versus Trabeculectomy

Gepubliceerd: 06-02-2020 Laatst bijgewerkt: 19-03-2025

The hypothesis is that the MicroShunt will lead to a similar IOP lowering compared to trabeculectomy, and will be a cost-effective alternative for trabeculectomy.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20100

Bron
Nationaal Trial Register

Verkorte titel
MS vs TE

Aandoening

Primary open-angle glaucoma

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: ZonMw 852001908

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

The standard surgical treatment for glaucoma is trabeculectomy. The PRESERFLO™ (formerly InnFocus) MicroShunt is a new, minimally invasive drainage device which has been suggested to result in similar intraocular pressure 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.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) compared to trabeculectomy.
This is a multicenter, randomized, single blind, non-inferiority, interventional clinical trial, involving 10 medical centres in the Netherlands.

Doel van het onderzoek

The hypothesis is that the MicroShunt will lead to a similar IOP lowering compared to trabeculectomy, and will be a cost-effective
alternative for trabeculectomy.

Onderzoeksopzet

preoperative visit, 1 day, 1 week, 4 weeks, 3, 6, 9 and 12 months postoperative.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Caucasian, primary open angle glaucoma patients, between 18 and 80 years old, requiring standard trabeculectomy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.
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.
5. Any ocular comorbidities that could affect the visual field. .
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.
9. Conditions that increase the risk of endophthalmitis.
10. Contraindication or allergy to mitomycin C.
11. Any contraindication to tube placement.
12. Use of oral hypotensive glaucoma medications for treatment of the fellow eye.
13. Prior ocular laser treatment within 3 months of the surgery.
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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-02-2020
Aantal proefpersonen:	196
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-02-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52755
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8356
CCMO	NL68964.068.19
OMON	NL-OMON52755

Resultaten