A Randomized Study Comparing the Safety and Efficacy of the InnFocus MicroShunt® Glaucoma Drainage System to Standard Trabeculectomy In Subjects with Primary Open Angle Glaucoma

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

Summary

ID

NL-OMON46024

Source
ToetsingOnline

Brief title
InnFocus MicroShunt Versus Trabeculectomy Study

Condition

- Glaucoma and ocular hypertension

Synonym
intraocular pressure, lowering the pressure in the eye

Research involving
Human

Sponsors and support

Primary sponsor: InnFocus, Inc.
Source(s) of monetary or material Support: InnFocus;Inc.

Intervention

Keyword: Eye Diseases, Glaucoma, Ocular Hypertension, Open-Angle

Outcome measures

Primary outcome

The primary effectiveness outcome is the proportion of eyes with >= 20% decrease in mean diurnal intraocular pressure from screening to 12 months post-operative examination.

The proportion of eyes with >= 20% decrease in mean diurnal intraocular pressure from screening to 24 months follow-up will also be compared between treatment group and control group.

Secondary outcome

The secondary effectiveness outcome is the mean diurnal IOP change from screening to 12 months follow-up.

The mean diurnal IOP change from screening to 24 months post-operative examination will also be compared between the treatment group and control group.

Study description

Background summary

Primary open-angle glaucoma is a significant public health problem. It is estimated that 45 million people in the world have open-angle glaucoma (OAG). Glaucoma (both open-angle and angle-closure) is the second leading cause of

blindness worldwide, with approximately 8.4 million people blind from glaucoma. Overall in 2004, the prevalence of POAG for adults 40 and older in the United States was estimated to be about 2%. Open-angle glaucoma affects an estimated 2.2 million people in the United States, and that number is likely to increase to 3.3 million in 2020 as the population ages. However, large differences exist in the prevalence of glaucoma among different ethnic groups. Overall, there appears to be a threefold higher prevalence of OAG in African Americans relative to non-Hispanic Whites in the United States. It is also the leading cause of blindness in African Americans. Further, the prevalence of OAG is even higher in Afro-Caribbeans relative to African Americans. Recent evidence on Hispanics/Latinos suggests that they have high prevalence rates of OAG that are comparable to African Americans. There are no data on the prevalence of OAG in Asians in the United States.

The findings of epidemiological investigations and clinical trials provide a framework for assessing the risk factors associated with POAG.

Study objective

The study objective is to assess the safety and effectiveness of the InnFocus MicroShunt when used to lower intraocular pressure (IOP) in subjects with primary open angle glaucoma where the IOP is not controlled when using maximum tolerated glaucoma medications.

Study design

This is a prospective, randomized, controlled, single-masked, multicenter trial. Two study groups will be included in the study. The treatment group consists of subjects who receive the InnFocus MicroShunt with Mitomycin C (MMC). The control group consists of subjects who receive trabeculectomy with MMC. The study will consist of two phases.

In the initial phase (Phase I), 102 subjects (68 treatments and 34 controls, 2:1 randomization ratio) were randomized. After 75 initial-phase subjects (about 50 treatments and 25 controls) completed the 3-month follow-up examination, all data was submitted to the FDA to request approval for expansion (Phase II) to the full study population of an additional 412 randomized subjects (approximately 309 treatments and 103 controls, 3:1 randomization ratio). Subsequently an expansion of Phase II was granted for another 102 patients with the same randomization schedule (3:1) for a total of 514 Phase II patients. Phase I patients will be analyzed as a feasibility cohort separately from Phase II.

A total of 514 subjects will be randomized in Phase II at 3:1 ratio, with a drop-out rate of 6% per year, approximately 480 randomized subjects in Phase II (360 treatments and 120 controls) are expected to have the 12-month examination

and 448 randomized subjects (336 treatments and 112 controls) are expected to have the 24-month follow-up examination.

The randomization will be stratified by investigational site and within-site by lens status with a target of at least 60 randomized phakic eyes in the treatment group and 20 randomized phakic eyes in the control group at 24 months.

Intervention

InnFocus MicroShunt Surgical Procedure

Study burden and risks

Burden: the scheduled visits at the study doctor (see also questions E3 and E3a).

Risks: possible side effects of the study procedure (see also question E9).

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

1. Male or female patient, age 40 to 85 years, inclusive
2. Early to severe primary open angle glaucoma where the mean diurnal intraocular pressure is not controlled on maximum tolerated medical therapy with intraocular pressure >= 15 mm Hg and <= 40 mm Hg while on glaucoma medications. Maximum tolerated medical therapy is defined as:
a. Three or more classes of topical glaucoma medications (prostaglandin analog, beta-adrenergic antagonist, carbonic anhydrase inhibitor, alpha-adrenergic agonist, parasympathomimetic). Combination glaucoma medications that consist of two or more glaucoma drugs will have each glaucomadrug component counted as a separate drug.
b. fewer than three classes presently in use if a subject*s intolerance to specific glaucoma medications and ineffective medications are included.
3. Primary open angle glaucoma diagnosis based on:
a. visual field mean deviation of -3dB or worse and
b. glaucomatous optic nerve damage as evidenced by any of the following optic disc or retinal nerve fiber layer structural abnormalities documented on slit lamp stereo biomicroscopy or in stereo disc photos:
* Diffuse thinning, focal narrowing, or notching of the optic disc rim, especially at the inferior or superior poles
* Localized abnormalities of the peripapillary retinal nerve fiber layer, especially at the inferior or superior poles
* Optic disc neural rim asymmetry of the two eyes consistent with loss of neural tissue
* Disc rim or peripapillary retinal nerve fiber layer hemorrhages.
4. Prior ab interno conjunctival-sparing glaucoma procedures were conducted more than 6 months prior to enrolment (e.g., iStent, Trabectome, gonioscopy-assisted transluminal trabeculectomy [GATT]).
5. Patient must have signed and dated the Informed Consent form.
6. Patient is willing to attend follow-up visits for two years postoperatively.

Exclusion criteria

1. Patient unwilling or unable to give informed consent, unwilling to accept randomization, or unable to return for scheduled protocol visits through 2 years.
2. Patient < 40 years or >85 years of age.
3. Patient is pregnant or nursing or unable to use appropriate birth control.
4. Vision level of no light perception.
5. Active iris neovascularization, active proliferative retinopathy or other ophthalmic disease

that could confound study results.
6. Iridocorneal endothelial syndrome.
7. Epithelial or fibrous downgrowth.
8. Secondary glaucoma such as post-trauma, pseudoexfoliation or pigment dispersion.
9. Chronic ocular inflammatory disease.
10. Subject already enrolled in this or another study (only one eye can participate in this study) or completed their participation in another study within 30 calendar days of the screening exam.
11. Aphakia.
12. Vitreous in the anterior chamber.
13. A history of corneal surgery (including Lasik or PRK), corneal opacities or disease/pathology if accurate IOP measurement may be affected. (Active corneal infection or Fuchs dystrophy are examples.)
14. Severe anterior or posterior blepharitis.
15. Unwilling to discontinue contact lens use after surgery for the duration of the study.
16. Previous incisional ophthalmic surgery involving the conjunctiva.
17. Prior clear corneal cataract, angle or trabecular meshwork surgery conducted within the past 6 months (e.g., iStent, Trabectome, gonioscopy-assisted transluminal trabeculotomy)
18. Presence of an anterior chamber IOL (ACIOL).
19. Prior laser peripheral iridotomy conducted within three months of enrollment.
20. Need for glaucoma surgery combined with other ocular procedures or anticipated need for additional ocular surgery during the investigational period.
21. Fellow eye with poorer than 20/80 best-corrected visual acuity (BCVA) or points in both hemifields within 5 degrees of fixation with sensitivity less than <0 dB.
22. Known allergy or other contraindication to mitomycin C (MMC) drug.
23. Angle closure glaucoma or narrow anatomical chamber angle as identified by gonioscopy and classified as Shaffer Grade 0 or 1.
24. Endothelial cell density at screening for the central reading of the following values:
- Phakic
* Age 40-45< 2200 cells/mm2
* Age 46-55 < 2000 cells/mm2
* Age 56-65 < 1800 cells/mm2
* Age over 65 < 1600 cells/mm2
- Pseudophakic
* Age 40-45 < 1980 cells/mm2
* Age 46-55 < 1800 cells/mm2
* Age 56-65 < 1620 cells/mm2
* Age over 65 < 1440 cells/mm2
25. Any condition that prevents the investigational device implantation or trabeculectomy in the superior region of the study eye (e.g., peripheral anterior synechiae, scleral staphyloma or conjunctival scarring).
26. Diagnosed degenerative visual disorders not associated with existing glaucoma condition (e.g., advanced dry or wet macular degeneration or other retinal disorders, central retinal artery or vein occlusion) or choroidopathy (e.g., choroidal detachment, effusion, choroiditis, or neovascularization).
27. Central corneal thickness that is less than 450 microns or greater than 620 microns.
28. Previous cyclodestructive procedure

29. Prior retinal laser procedure conducted for any purpose other than treatment of retinal tear or hole.
30. Conditions associated with elevated episcleral venous pressure such as active thyroid orbitopathy, cavernous sinus fistula, Sturge-Weber syndrome, orbital tumors, orbital congestive disease.
31. Clinically significant sequelae from trauma (e.g., chemical burns, blunt trauma, etc.)
32. Ocular pathology or medical condition for which, in the investigator's judgment, the following factors would either place the subject at increased risk of complications or contraindicate device implantation or interfere with compliance to elements of the study protocol (e.g., ophthalmic examinations, follow-up visits),
a. inability to reliably complete visual field testing over the course of the study,
b. uncontrolled systemic disease (e.g. diabetes, hypertension) that could compromise their participation in the study.
c. Disorders that pose a fall risk, as well as compromise ability to take a visual field exam and take glaucoma medications (e.g., Parkinson's disease),
d. inability to discontinue use of blood thinners.
e. immunodeficiency concerns.
f. known corticosteroid responders whose pressure increases would not allow them to withstand the postop corticosteroid regimen.
33. Intraocular silicone oil.
34. Ocular steroid use in the planned study eye or systemic steroid use anytime within three months of the procedure. (This would not include the use of inhaled or dermatologic steroids.)
35. Completion of chemotherapy within six months of the screening visit.
36. Use of oral hypotensive glaucoma medications for treatment of fellow eye.
37. A requirement of general anesthesia for the procedure.
38. ALT/SLT within 90 days of enrollment.

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:	Recruitment stopped
Start date (anticipated):	22-02-2017
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	InnFocus MicroShunt® Glaucoma Drainage System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-02-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-09-2017
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01881425
CCMO	NL56161.068.16