A Prospective, Concurrent Controlled, Open-Label, Multicenter Clinical Study to Assess the Long-Term Safety of the PRESERFLO® MicroShunt in Subjects with Primary Open-Angle Glaucoma Who Have Completed Participation in the INN-005 Randomized Controlled Study.

Published: 24-09-2020
Last updated: 09-04-2024

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

Summary

ID

NL-OMON55019

Source
ToetsingOnline

Brief title
Long-Term Safety of the PRESERFLO® MicroShunt

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

Primary Safety Outcome Measure: • Incidence of sight-threatening adverse events.

Secondary outcome

Secondary Outcome Measures - Safety: • Incidence of ocular adverse events in the study eye. • Incidence of needling and reoperations for glaucoma (e.g. trabeculectomy, repositioning or explantation of PRESERFLO® MicroShunt, bleb revision, glaucoma drainage device, or other incisional treatment to establish a new aqueous flow path from the anterior chamber in order to maintain acceptable IOP, iridectomy, re-suturing of scleral flap, glaucoma laser surgery). • Change in Best Corrected Visual Acuity (BCVA) from INN-005 study screening, as measured by ETDRS. • Change in visual field mean deviation from INN-005 study screening. • Change in central corneal thickness from INN-005 study screening as assessed by ultrasound pachymetry. • Change in central corneal endothelial cell density from INN-005 study screening as assessed by specular microscopy. • Change in lens opacity for phakic lens from INN-005 study screening as assessed by LOCS III classification system. • Ophthalmologic

examinations findings Secondary Outcome Measures - Effectiveness: • Proportion of study eyes with >= 20% decrease in intraocular pressure (IOP), from INN-005 study screening, without increasing the number of glaucoma medications. • Mean change in IOP from INN-005 study screening. • Proportion of study eyes with any qualifying glaucoma-related post-operative intervention. • Proportion of study eyes considered a treatment success (total, complete, qualified). • Change in the number of glaucoma medications from INN-005 study screening.

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.
Extension study: The purpose of this study is to evaluate the long-term safety of the PRESERFLO® MicroShunt in subjects with Primary Open-Angle Glaucoma who have completed participation in the INN-005 clinical study, conducted under IDE G130028, by collecting safety data through 5 years post-operative follow-up.

Study objective

The purpose of this study is to evaluate the long-term safety of the PRESERFLO®

MicroShunt in subjects with Primary Open-Angle Glaucoma who have completed participation in the INN-005 clinical study, conducted under IDE G130028, by collecting safety data through 5 years post-operative follow-up.

Study design

The study is a prospective, concurrent controlled, open-label, multicenter study designed to collect safety data through 5 years of follow-up for subjects randomized to the treatment and control arms of the INN-005 study.

Intervention

None

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.Subject has completed their Month 24 Follow-Up Visit in the INN-005 clinical study conducted under IDE G130028. 2. Subject was randomized into the INN-005 study and received the PRESERFLO® MicroShunt deviceor trabeculectomy. (Subjects who have had the device explanted, or replaced with another device, may be included). 3. Subject is willing and able to comply with all study requirements, including signing an informed consent form.

Exclusion criteria

1. Subject has exceeded the timeframe for the Month 60 Follow-Up Visit prior to enrollment for participation in this long-term follow-up study.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2021
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-02-2022
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04333433
CCMO	NL74299.068.20