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Safety and efficacy of Transcend CyPass glaucoma implant in open angle glaucoma patients who have failed medical treatment

Submission date	Recruitment status	[ ] Prospectively registered
18/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/06/2010	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TMI-07-01

Study information

Scientific Title
A pilot study to assess the safety and efficacy of the Transcend CyPass glaucoma implant in patients with open angle glaucoma who have failed medical treatment

Study objectives
The objective of the study is to evaluate the safety and effectiveness of the Transcend CyPass implant in patients with primary open-angle glaucoma (POAG) who have failed intraocular pressure (IOP) management on maximally tolerated medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Western Institutional Review Board (WIRB) approved on the 20th April 2008

Study design
Open-label prospective study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary open angle glaucoma

Interventions
Transcend CyPass implant used to treat primary open-angle glaucoma. The patients will be followed for 12 months following surgery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Efficacy will be evaluated as change in IOP from the pre-operative baseline, absolute and relative, proportion of patients with an IOP of 21 mmHg or less, and change in the number of glaucoma medications. This will be done based on the 3 month visit results. Subsequent data (6 months and 12 months) will be collected as confirmatory.

Secondary outcome measures
Safety will be evaluated by ocular signs and symptoms, (best corrected) visual acuity, biomicroscopy, ophthalmoscopy and gonioscopy, as well as by adverse events. Progression of glaucomatous field defects will also be a safety measure (see analysis of visual field progression).

All measured at 12 months.

Overall study start date
20/08/2008

Completion date
20/08/2009

Eligibility

Key inclusion criteria
1. Males or females 18 years of age or older
2. Diagnosis in the study eye of primary open angle glaucoma (POAG) or open angle glaucoma associated with pseudoexfoliation syndrome or pigmentary glaucoma
3. Patients able to understand the requirements of the study and willing to follow study instructions, to provide written informed consent to participate, and who agree to comply with all study requirements, including the required study follow-up visits
4. Intra-ocular pressure (IOP) of greater than or equal to 21 mmHg and less than or equal to 40 mmHg while on maximal tolerated medical therapy, documented at two sequential visits at any time of day, at least 48 hours apart, within 45 days prior to surgery
5. Patients must sign and witness the current Informed Consent Document
6. Patients must have sufficient space of the angle to accommodate the device

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 patients

Key exclusion criteria

1. Visual acuity of light perception or less in the study eye
2. Any previous surgery for any aqueous shunt device
3. Prior laser treatment of the retina
4. Any ophthalmic surgery performed within three months prior to study
5. Diagnosis of angle closure following penetrating keratoplasty, neovascular glaucoma, congenital glaucoma, developmental glaucoma, previous goniotomy, "active" uveitis within six months, or other secondary glaucomas (except pseudoexfoliation syndrome or pigmentary glaucoma, which are allowed)
6. Best corrected visual acuity (BCVA) less than 20/200 in the fellow eye
7. Active diabetic retinopathy
8. Clinically significant inflammation or infection within six months prior to study
9. Uncontrolled systemic disease (e.g., diabetes, hypertension, etc.) in the opinion of the Investigator
10. Participation in any study involving an investigational drug within the past 45 calendar days, or ongoing participation in a study with an investigational device
11. Intolerance or hypersensitivity to topical anesthetics, mydriatics, or components of the device
12. A medical condition, serious intercurrent illness, or extenuating circumstance that would significantly decrease study compliance, including all prescribed follow-up
13. Any condition that, in the opinion of the investigator, would jeopardize the safety of the patient
14. Female patients of childbearing potential less than 1 year postmenopausal, and not surgically sterilised, who are not on a medically-acceptable form of birth control

Date of first enrolment
20/08/2008

Date of final enrolment
20/08/2009

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
Transcend Medical
Irvine
United States of America
92618

Sponsor information

Organisation
Transcend Medical, Inc.™ (USA)

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Sponsor type
Industry

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ROR
https://ror.org/028fhxy95

Funder(s)

Funder type
Industry

Funder Name
Transcend Medical, Inc.™ (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration