

Transcend CyPass glaucoma implant and cataract surgery in open angle glaucoma patients

Submission date 18/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 17/06/2010	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

TMI-08-01C

Study information

Scientific Title

A pilot study to assess the safety and efficacy of the Transcend CyPass glaucoma implant in combination with cataract surgery in patients with open angle glaucoma

Study objectives

The objectives of the study are to evaluate the safety and effectiveness of the Transcend CyPass implant in combination with cataract surgery in patients with primary open-angle glaucoma (POAG).

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics approval required as this was a prospective registry study with no interventions.

Study design

Open-label controlled prospective pilot 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, ocular hypertension

Interventions

Group 1: eyes will undergo both cataract surgery and CyPass implantation and patients will be followed for 12 months following surgery.

Group 2: eyes will undergo only cataract surgery and patients will be followed for 12 months following surgery.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Measured at 12 months:

1. Best corrected visual acuity
2. Intraocular pressure (IOP)
3. Manifest refraction
4. Biomicroscopy
5. Gonioscopy
6. Ophthalmoscopy (dilated)

Secondary outcome measures

No secondary outcome measures

Overall study start date

30/04/2008

Completion date

30/04/2009

Eligibility

Key inclusion criteria

1. Patients must be age 18 or over, either sex
2. Patients must have diagnosis of primary open angle glaucoma or ocular hypertension (OHT). Also acceptable are patients diagnosed with open angle glaucoma associated with pseudoexfoliation syndrome or pigmentary glaucoma.
3. Candidacy for cataract surgery in the study eye as determined by the clinical judgment of the investigator
4. Patients who have had previous trabeculoplasty glaucoma procedures such as argon laser trabeculoplasty (ALT) or selective laser trabeculoplasty (SLT)
5. Patients must have intraocular 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 30 days prior to surgery
6. Patients must have sufficient space in the angle to accommodate the device
7. Patients must be able to understand the requirements of the study and be 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

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20 patients

Key exclusion criteria

1. Patients with previous glaucoma surgery, including trabeculectomy or implantation of any aqueous shunt device, or the following glaucoma surgeries: viscocanulostomy, cyclophotocoagulation, or collagen implant
2. Patients with any ophthalmic surgery within 3 months in the eye to be treated
3. Patients with diagnosis of angle closure following penetrating keratoplasty, neovascular glaucoma, congenital glaucoma, developmental glaucoma or previous goniotomy
4. Patients with active uveitis within six months or other secondary glaucomas (other than pseudoexfoliation syndrome or pigmentary glaucoma)
5. Patients with best corrected visual acuity less than 20/200 in the fellow eye
6. Patients with clinically significant inflammation or infection within 6 months prior to the study
7. Patients with active diabetic retinopathy
8. Patients who have any uncontrolled systemic disease (e.g., diabetes, hypertension, etc.) in the opinion of the investigator
9. Intolerance or hypersensitivity to topical anesthetics, mydriatics, or components of the device
10. A medical condition, serious illness, or extenuating circumstance that would significantly decrease study compliance, including all prescribed follow-up
11. Any condition that, in the opinion of the investigator, would jeopardize the safety of the patient
12. Participation in any study involving an investigational drug within the past 30 calendar days, or ongoing participation in a study with an investigational device
13. Patients who are pregnant or planning to be pregnant during the course of the study

Date of first enrolment

30/04/2008

Date of final enrolment

30/04/2009

Locations

Countries of recruitment

Malaysia

Mexico

Philippines

United States of America

Study participating centre

Transcend Medical

Irvine

United States of America

92618

Sponsor information

Organisation

Transcend Medical, Inc.™ (USA)

Sponsor details

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Sponsor type

Industry

Website

<http://www.transcendmedical.com/index.htm>

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