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

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

Protocol serial number
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.

Primary study design
Interventional

Study design
Open-label controlled prospective pilot study

Study type(s)
Treatment

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(s)
Measured at 12 months:
1. Best corrected visual acuity
2. Intraocular pressure (IOP)
3. Manifest refraction
4. Biomicropscopy
5. Gonioscopy
6. Ophthalmoscopy (dilated)

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/028fhxy95

Funder(s)

Funder type
Industry

Funder Name
Transcend Medical, Inc.™ (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration