

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

<b>Submission date</b> 18/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/06/2010	<b>Condition category</b> 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-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)

**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