

A multicentre registry study to capture data with respect to CyPass clinical experience (CYCLE)

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 07/09/2011	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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

TMI-09-02

Study information

Scientific Title

Long-term safety, effectiveness and clinical experience of the CyPass glaucoma implant when used in the standard clinical environment: a multicentre registry study with retrospective and/or prospective data capture

Study objectives

The purpose of this research study is to evaluate the long-term safety, effectiveness and clinical experience of the CyPass implant in glaucomatous eyes when used in accordance with the product instructions for use (IFU) in the standard clinical environment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Germany:
 - 1.1. FEKI approved on the 15th December 2009
 - 1.2. Ruhr University approved on the 19th February 2009
 - 1.3. Universitat Greifswald approved on the 27th January 2010
2. Poland: Ethics Committee at Military Medical Institute approved on the 21st April 2010

Study design

Multicentre registry study with retrospective and/or prospective data capture

Primary study design

Interventional

Secondary study design

Multi-centre

Study setting(s)

GP practice

Study type(s)

Other

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

Glaucoma

Interventions

The total duration of the treatments was 12 months. Observations and assessments included best corrected visual acuity (BCVA, Snellen), tonometry, slit lamp exam and adverse event assessment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Safety outcomes: Incidence of intra-operative and post-operative adverse events

Secondary outcome measures

Effectiveness Outcomes:

1. Mean change in IOP from baseline to 1 month post-operatively, and beyond
2. Mean change in required glaucoma medications used from baseline to 1 month post-operatively, and beyond

Overall study start date

15/12/2009

Completion date

15/12/2011

Eligibility

Key inclusion criteria

1. Able to understand study requirements and willing to follow study instructions and provide written consent
2. Diagnosis of glaucoma in the study eye
3. At the preoperative visit, a mean medicated or unmedicated intraocular pressure (IOP) in the study eye of greater than or equal to 18 mmHg and less than or equal to 44 mmHg

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

Up to 500 subject eyes enrolled at up to 20 study sites

Key exclusion criteria

1. Diagnosis of acute angle closure, narrow angle, uveitic or neovascular glaucoma in the study eye
2. Diagnosis of normal tension glaucoma in the study eye

Date of first enrolment

15/12/2009

Date of final enrolment

15/12/2011

Locations

Countries of recruitment

Bulgaria

Germany

Italy

Poland

Spain

United States of America

Study participating centre

Transcend Medical

Irvine

United States of America

92618

Sponsor information

Organisation

Transcend Medical, Inc.™ (USA)

Sponsor details

c/o Ginger Clasby

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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.TM (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