ISRCTN74288501 https://doi.org/10.1186/ISRCTN74288501

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

Submission date
18/05/2010

Recruitment status
No longer recruiting

Registration date
17/06/2010

Overall study status
Completed

Last Edited
07/09/2011

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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-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

Study type(s)
Other

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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)

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