

Dilation of Schlemm's Canal during Glaucoma Surgery

Submission date 30/08/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/01/2012	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OMS-2005

Study information

Scientific Title

Dilation of Schlemms Canal during Glaucoma Surgery: A multicenter, single arm, non-randomized interventional trial

Study objectives

That the use of the iScience microcatheter in the treatment of open angle glaucoma is safe and effective.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Freiburg Ethics Commission International (FECI) approved on the 8th of September 2005 (ref: 05/1462)

Study design

Prospective multicentre single arm non-randomised interventional trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Please contact the Clinical Affairs Department [clinical@iscienceinterventional.com] for more information or to request a patient information sheet

Health condition(s) or problem(s) studied

Open-angle glaucoma

Interventions

Canaloplasty, a procedure involving circumferential viscodilation and tensioning of the inner wall of Schlemms canal for the treatment of open-angle glaucoma This is a single-arm study. The total duration of follow-up is 3 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Intraocular pressure in mm Hg, measured at baseline, 1 day, 1 week, and then at 1, 3, 6, 12, 18, 24, 30, and 36 months using tonometry.

2. Number of glaucomatous medications, obtained during patient visits and recorded via case report forms.

Secondary outcome measures

1. Nature and frequency of surgical and post-surgical complications
 2. Number of secondary interventions
- Obtained during patient visits and recorded via case report forms.

Overall study start date

08/09/2005

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. At minimum 18 years of age
2. Scheduled for glaucoma surgery or combined cataract and glaucoma surgery
3. Diagnosis of primary open-angle glaucoma (POAG), pigmentary glaucoma, exfoliative glaucoma, or POAG mixed with another included mechanism
4. Baseline intraocular pressure of 16 mm Hg or higher and a historical IOP of 21 mm Hg or higher
5. Either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

157 eyes

Key exclusion criteria

1. Neovascular disease
2. Uveitis
3. Peripheral anterior synechiae
4. Angle recession
5. Developmental or secondary glaucoma with the exception of pigmentary and exfoliative glaucoma
6. Previous ocular surgeries that would interfere with complete circumferential catheterization of Schlemms canal
7. Patients with more than two laser trabeculoplasty procedures

Date of first enrolment

08/09/2005

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Germany

United States of America

Study participating centre

4055 Campbell Ave.

Menlo Park

United States of America

94025

Sponsor information

Organisation

iScience Interventional Corp. (USA)

Sponsor details

4055 Campbell Ave

Menlo Park

United States of America

94025

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

iScience Interventional Corp (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2011		Yes	No