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Dilation of Schlemm's Canal during Glaucoma Surgery

Submission date	Recruitment status	[_] Prospectively registered
30/08/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/01/2012	Eye Diseases	

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 muticenter, 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 or 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
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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