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Influence of topical anti-VEGF (Ranibizumab) on the outcome of filtration surgery for glaucoma

Submission date 10/08/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/08/2010	**Overall study status** Completed	
Last Edited 26/05/2011	**Condition category** 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
2009DR2127

Study information

Scientific Title
Influence of topical anti-VEGF (Ranibizumab) on the outcome of filtration surgery for glaucoma: A two phased study with a randomised placebo controlled trial

Study objectives
This is a two phased study in patients who underwent trabelculectomy with mitomycin C combined with phacoemulsification and intra ocular lens (IOL) implantation.
1. Assessing the local tolerability and safety of topical ranibizumab
2. Assessing the efficacy of topical ranibizumab against placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The local Ethics committee approved on the 24th of October 2008
2. Swissmedic, the Swiss Food and Drug Administration approved on the 25th of June 2009 (ref: 2009DR2127)

Study design
Phase I: Follow-up study
Phase II: Randomised Controlled Trial

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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Glaucoma, patients with excessive wound healing after trabeculectomy.

Interventions
Topical ranibizumab eyedrops (2mg/ml) four times daily for 1 month or placebo (BSS 4x/d for 1 month

Intervention Type
Other

Phase
Phase II/III

Primary outcome measure
Differences in the intraocular eye pressure, measured at 4 weeks, 3 and 6 months

Secondary outcome measures
1. Bleb appearance / vascularisation using a standardized photography and the Moorfields bleb grading system
2. Postoperative intraocular pressure
3. Conjunctival wound healing problems
All outcomes will be measured at 4 weeks, 3 and 6 months.

Overall study start date
01/01/2011

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Patients with primary open angle glaucoma (POAG), PEX and pigment dispersion Glaucoma
2. At least 18 years of age
3. No previous intraocular surgery undergoing trabeculectomy or phaco-trabeculectomy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 patients, 25 in each arm

Key exclusion criteria
1. Patients with primary angle closure glaucoma (PACG)
2. Glaucoma due to other causes
3. Previous intra- and extraocular surgery
4. Any surgery during the last 3 months
5. Patients with uveitis or inflammatory ocular surface disease
6. Patients with single eyes
7. Patients presenting the first postoperative day with bleb leak, hypotony or situations that potentially need another surgery
8. Pregnant and breast feeding women
9. Women planning to get pregnant

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Switzerland

Study participating centre
Augenklinik
Lucerne
Switzerland
6000

Sponsor information

Organisation
Horten Center, University of Zurich (Switzerland)

Sponsor details
c/o Prof Lucas Bachmann
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Sponsor type
Not defined

ROR
https://ror.org/01462r250

Funder(s)

Funder type
Charity

Funder Name

Horten Center, University of Zurich (Switzerland) - core funding

Funder Name
Lucerne Eye Clinic (Switzerland) - core funding

Funder Name
Novartis (Switzerland) - providing active medications

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?
Protocol article	protocol	17/01/2011		Yes	No