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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Frank Bochmann

Contact details

Augenklinik Luzerner Kantonsspital CH-6000 Luzern 16 Lucerne Switzerland 6000

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 eves
- 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 Postfach Nord USZ CH-8091 Zurich Switzerland 8091

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