

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

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

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

Protocol serial number
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 trabeculectomy 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)

Primary study design

Interventional

Study design

Phase I: Follow-up study

Phase II: Randomised Controlled Trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Augenlinik

Lucerne

Switzerland

6000

Sponsor information

Organisation

Horten Center, University of Zurich (Switzerland)

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

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