# 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	
Registration date	Overall study status	Statistical analysis plan	
18/08/2010	Completed  Condition category	Results	
Last Edited		Individual participant data	
26/05/2011	Eye Diseases	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

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# 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 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

# 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 Augenklinik

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 adde	d Peer reviewed?	Patient-facing?
Protocol article	protocol	17/01/2011	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	5 No	Yes