

# Subconjunctival bevacizumab on eyes with recent onset of cornea neovascularisation

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
06/09/2010	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
25/10/2010	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
01/11/2013	Eye Diseases	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

PETC1002

## Study information

### Scientific Title

Pilot randomised placebo-controlled double-masked clinical trial of subconjunctival bevacizumab on eyes with recent onset of cornea neovascularisation

### Study objectives

Subconjunctival bevacizumab is additionally effective to topical preservative free dexamethasone 0.1% in the treatment of recent onset corneal neovascularisation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

National Research Ethics Service East London and the City Ethics Committee 1 approved on the 02/03/2009 (ref: 09/H0703/2)

**Study design**

Prospective placebo-controlled double-masked randomised clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Corneal neovascularisation

**Interventions**

The intervention is subconjunctival bevacizumab or placebo by subconjunctival injection. The treatment protocol for each intervention will be:

1. Subconjunctival bevacizumab (active arm): a volume of 0.1 ml of 25 mg/ml bevacizumab will be injected into the subconjunctival space 2 mm from the limbus at the area of most active neovascularisation. Injections will be repeated at week 4 and 8 unless prevented by any adverse event.
2. Subconjunctival saline (placebo arm): a syringe exactly the same in appearance to the above bevacizumab treatment will be prepared by Pharmacy but containing only 0.1 ml of normal saline solution. This will be injected by the same investigator, blinded to the contents of the syringe.

Conventional treatment:

Standard therapy be given to all patients and is will involve defined as dexamethsone 0.1% preservative free solution to be instilled at 4 times per day for the first month and then increasing or decreasing according to neovascularisation response.

**Intervention Type**

Drug

**Phase**

Phase II/III

**Drug/device/biological/vaccine name(s)**

Bevacizumab, dexamethasone

**Primary outcome(s)**

Change in area of corneal neovascularisation at 3 months compared to baseline by image analysis of digital slit lamp photos

### **Key secondary outcome(s)**

Measured from baseline to 3 months:

1. Change in visual acuity
2. Change in corneal signs including:
  - 2.1. Presence of and size of epithelial defects
  - 2.2. Signs of corneal melting or thinning using pentacam
  - 2.3. Lipid keratopathy
  - 2.4. Central endothelial cell counts using specular microscopy
  - 2.5. Changes in lumen diameter of main vessels
  - 2.6. Indirect assessments of vessel permeability change in area of lipid keratopathy, corneal clarity by pentacam imaging
3. Change in normal conjunctival blood vessels. Systematic digital photos of 4 quadrants of each patients conjunctiva will also be taken and compared after 3 months of treatment. The aim is to see whether bevacizumab may have an effect in reducing normal blood vessels during the treatment period compared to the control group.
4. The proportion of adverse events in each arm
5. Physician assessment of improvement compared with digital assessment

### **Completion date**

16/08/2010

## **Eligibility**

### **Key inclusion criteria**

1. Male or female over 18 years of age
2. Presence of blood vessels extending 2 mm from the limbus onto the cornea
3. Co-existent corneal condition causing neovascularisation that is present for no more than 6 months
4. Ability to understand and provide consent to participate in the study and willingness to follow study instructions and likely to complete all required visits

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

## **Key exclusion criteria**

1. Patients with corneal neovascularisation of greater than 6 months duration
2. Presence of corneal conditions that may be worsened with bevacizumab including active corneal melting, persistent epithelial defects, active infective keratitis
3. A history of cardiovascular or cerebro-vascular event in the previous 6 months
4. Uncontrolled hypertension defined as systolic blood pressure greater than 160 mmHg or diastolic blood pressure greater than 90mmHg
5. Pregnancy or breastfeeding
6. Current or recent (less than 3 months) use of bevacizumab into the study eye
7. Patient with history of steroid responsiveness or uncontrolled intraocular pressure
8. Subject hypersensitive to bevacizumab

## **Date of first enrolment**

27/04/2009

## **Date of final enrolment**

16/08/2010

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

162 City Road

London

United Kingdom

EC1V 2PD

## **Sponsor information**

### **Organisation**

Moorfields Eye Hospital NHS Foundation Trust (UK)

### **ROR**

<https://ror.org/03zaddr67>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

**Funder Name**

Special Trustees of Moorfields Eye Hospital (UK) (awarded 05/01/2009; ref: PETC1002)

## 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?
<a href="#">Results article</a>	results	01/01/2013		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes