

Subconjunctival bevacizumab on eyes with recent onset of cornea neovascularisation

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

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Stephen Tuft

Contact details

162 City Road
London
United Kingdom
EC1V 2PD
s.tuft@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 hypothesis

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

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 measure

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

Secondary outcome measures

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

Overall study start date

27/04/2009

Overall study end date

16/08/2010

Eligibility

Participant 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

Participant 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

Recruitment start date

27/04/2009

Recruitment end date

16/08/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

162 City Road

London

United Kingdom

EC1V 2PD

Sponsor information

Organisation

Moorfields Eye Hospital NHS Foundation Trust (UK)

Sponsor details

162 City Road
London
England
United Kingdom
EC1V 2PD
Isabel.Moldon@moorfields.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.moorfields.nhs.uk/Home>

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

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?
Results article	results	01/01/2013		Yes	No
HRA research summary			28/06/2023	No	No