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Subconjunctival bevacizumab on eyes with recent onset of cornea neovascularisation

Submission date 06/09/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2010	**Overall study status** Completed	
Last Edited 01/11/2013	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 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

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

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 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 conjuncitval 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

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 form 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

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
England

United Kingdom

Study participating centre
162 City Road
London
United Kingdom
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Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust (UK)

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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