

# A pilot study to examine the safety and efficacy of posterior juxta-scleral (80 mg) triamcinolone acetonide, administration, in addition to Visudyne (verteporfin) photodynamic therapy for predominantly classic choroidal neovascularisation secondary to age-related macular degeneration: an open-label, randomised, active controlled trial

<b>Submission date</b> 04/11/2007	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/01/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/02/2012	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**

05NB13

## **Study information**

**Scientific Title**

### **Study objectives**

The aim of this study is to assess the effectiveness of posterior juxtascleral triamcinolone in reducing visual loss when used in conjunction with photodynamic therapy, for the treatment of exudative age related macular degeneration. We will be comparing the effect of the combined treatment against the standard treatment (Photodynamic Therapy [PDT]). The actions of triamcinolone are anti-inflammatory and anti-angiogenic. A beneficial effect of steroids in the eyes of patients with choroidal neovascularisation has been suggested in the literature.

As of 15/02/2012, the anticipated end date of trial was updated from 15/01/2008 to 01/11/2007. The trial was terminated early in November 2007 due to poor recruitment following the NICE approval of Lucentis for treatment of neovascular AMD.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the King's College Hospital Ethics Committee on the 29th January 2007 (ref no. 05NB13).

### **Study design**

Open-label, randomised, active controlled parallel group 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**

Macula degeneration

### **Interventions**

Patients are randomised to one of two treatments:

1. Patients receive Photodynamic Treatment (PDT) on their initial treatment visit. Follow up is every three months for a year with further PDT if required
2. Patients receive PDT and posterior juxtascleral injection of triamcinolone on their initial treatment visit. Follow up is every three months for one year. If required they will receive PDT on follow up visits

### **Intervention Type**

Drug

### **Phase**

Not Specified

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

Triamcinolone acetonide

### **Primary outcome measure**

The percentage of less than 15 letter loss at one year.

### **Secondary outcome measures**

1. Percentage of more than 30 letter loss at one year
2. Number of re-treatments required in one year
3. Change in lesion size at one year

### **Overall study start date**

16/01/2006

### **Completion date**

01/11/2007

### **Reason abandoned (if study stopped)**

"Participant recruitment issue"

## **Eligibility**

### **Key inclusion criteria**

1. Age 50 years or older, male and female
2. Clinical diagnosis of age-related macular degeneration (AMD)
3. Subfoveal choroidal neovascularisation (CNV) confirmed by fluorescein angiography
4. Best corrected visual acuity of 35 letters on Early Treatment Diabetic Retinopathy Study (ETDRS) chart

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

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

80

**Key exclusion criteria**

1. Inability to understand or sign consent form
2. The patient has a current medical condition or history of a medical condition that would be likely to preclude scheduled study visits
3. Patient has a current ophthalmic condition or history of an ophthalmic condition that might compromise the assessment of the treatment
4. Signs of a myopic retina or refraction of greater than -8 dioptres in their current or previous glasses prescription
5. Signs of other retinal conditions that may have caused the CNV such as angioid streaks, choroidal rupture, and old chorio-retinitis
6. Open angle glaucoma
7. At increased risk of developing glaucoma such as having; pigment dispersion syndrome or pseudoexfoliation
8. Unable to have a good quality fluorescein angiogram taken, e.g., due to head tremor or media opacity

**Date of first enrolment**

16/01/2006

**Date of final enrolment**

01/11/2007

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

King's College Hospital

London

United Kingdom

SE5 9RS

**Sponsor information**

**Organisation**

King's College Hospital (UK)

**Sponsor details**

Denmark Hill  
Camberwell  
London  
England  
United Kingdom  
SE5 9RS

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.kch.nhs.uk/>

**ROR**

<https://ror.org/01qz4yx77>

**Funder(s)****Funder type**

Industry

**Funder Name**

Novartis Pharmaceuticals UK Limited (UK)

**Funder Name**

King's Research Fund (UK)

**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