

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

Submission date 04/11/2007	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/01/2008	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/02/2012	Condition category 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

King's College Hospital

London

United Kingdom

SE5 9RS

Sponsor information

Organisation

King's College Hospital (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration