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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

Registration date
18/01/2008

Last Edited
15/02/2012

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 ofexudative age related macular degeneration. We will be comparing the effect of the combined treatment against the standard treatment (Photodynamic Therapy [PDT]).The actions of truamcinolone 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 follwing 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