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The safety and efficacy of posterior juxta-scleral (40 mg) or intra-vitreal (4 mg) triamcinolone acetonide, in addition to verteporfin photodynamic therapy for choroidal neovascularization (CNV), in age-related macular degeneration (AMD): a randomised controlled trial - STUDY STOPPED

Submission date 28/06/2005	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/09/2005	**Overall study status** Stopped	
Last Edited 07/09/2007	**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

Protocol serial number
NRR Pub ID N0503172670 (03428)

Study information

Scientific Title

Acronym
TPDT

Study objectives
To compare the effectiveness of (a) intra-vitreal and (b) posterior juxta-scleral triamcinolone acetonide as an adjunt to verteporfin photodynamic therapy for CNV secondary to AMD with (c) verteporfin photodynamic therapy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Choroidal neovascularization (CNV) secondary to Age-related macular degeneration (AMD)

Interventions
1. Posterior juxta-scleral (40 mg) triamcinolone acetonide + verteporfin photodynamic therapy
2. Intra-vitreal (4 mg) triamcinolone acetonide + verteporfin photodynamic therapy
3. Verteporfin photodynamic therapy alone

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Triamcinolone acetonide

Primary outcome(s)
Number of patients losing more than 15 letters (3 lines) of visual acuity (ETDRS logMAR chart at 2m) at 1 year.

Key secondary outcome(s))
1. Change in lesion size at one year
2. Number of re-treatments required in one year
3. Incidence of serious complications
4. Quality of life measures: NEIVFQ(25); SF-36
5. Contrast sensitivity threshold (Pelli-Robson contrast sensitivity chart)
6. Change in retinal thickness as shown on Ocular coherence tomography

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. The patient must be willing to give written informed consent
2. The patient must be able to undertake the necessary tests and treatment and be willing to be followed up
3. Age 50 years or older
4. Clinical diagnosis of AMD
5. Predominantly classic CNV on fluorescein angiography
6. Logarithm of the minimum angle of resolution (LogMAR) visual acuity of >35 letters on 2 m Early Treatment Diabetic Retinopathy Study (ETDRS) chart
7. Does not have open angle glaucoma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

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 such as unstable angina, dialysis, active cancer
3. Patient has a current ophthalmic condition or history of an ophthalmic condition that might compromise the assessment of the treatment such as diabetic retinopathy, uveitis, amblyopia, ischaemic optic neuropathy
4. Signs of a myopic retina or refraction of ≥8 diopters in their current or any previous glasses prescription
5. Signs of other retinal conditions that may have caused the CNV such as angiod streaks,

choroidal rupture, 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
9. Allergic to fluorescein or verteporfin or triamcinolone acetonide
10. Previous treatment for a retinal detachment
11. Judged by the examining clinician to be at increased risk of retinal detachment due to weaknesses in the peripheral retina
12. Previous photodynamic therapy or other therapy for a CNV including argon laser treatment
13. Patient is currently participating or has participated in a clinical trial that utilized an investigational drug or treatment within 30 days prior to enrolment to this study
14. On anticoagulation therapy such as warfarin, with the exception of aspirin and other anti-platelet therapy
15. <35 letters on the ETDRS logMAR chart
16. Inability to read a logMAR chart
17. Intraocular surgery in study eye within 60 days prior to planned enrolment in study

Date of first enrolment
01/10/2005

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Dept. Ophthalmology
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
The Newcastle upon Tyne Hospitals NHS Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Internally funded by participating centres. This study, although a separate randomised controlled trial requiring all the usual approvals, is nested within the UK Verteporfin Photodynamic therapy Cohort study. It will utilise the infrastructure of that study.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration