

# The safety and efficacy of posterior juxta-scleral (40 mg) or intra-vitreous (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

<b>Submission date</b> 28/06/2005	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/09/2007	<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

### Contact name

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NRR Pub ID N0503172670 (03428)

## Study information

Scientific Title

Acronym

TPDT

Study objectives

To compare the effectiveness of (a) intra-vitreous and (b) posterior juxta-scleral triamcinolone acetonide as an adjunct 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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-vitreous (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 measure

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

## Secondary outcome measures

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

## Overall study start date

01/10/2005

## 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

## Age group

Senior

**Sex**

Both

**Target number of participants**

400

**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  $\geq 8$  diopters in their current or any previous glasses prescription
5. Signs of other retinal conditions that may have caused the CNV such as angioid 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**

England

United Kingdom

**Study participating centre**

**Dept. Ophthalmology**  
Newcastle upon Tyne  
United Kingdom  
NE1 4LP

## **Sponsor information**

### **Organisation**

The Newcastle upon Tyne Hospitals NHS Trust (UK)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **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**

### **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