# Randomised Controlled Trial of Intravitreal Triamcinolone in Patients with Diabetic Macular Oedema Refractory to Laser Treatment

<b>Submission date</b> 30/09/2004	Recruitment status Stopped	<ul><li>Prospectively registered</li><li>Protocol</li></ul>
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Stopped	☐ Results
Last Edited	Condition category	Individual participant data
13/04/2011	Eye Diseases	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 N0192133909

# Study information

Scientific Title

## **Study objectives**

Does principal intravitreal injection of triamcinolone help in treating diabetic patients with clinically significant macular oedema that is refractory to the conventional focal or grid laser photocoagulation?

#### 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)

**Not Specified** 

#### Health condition(s) or problem(s) studied

Eye Diseases: Diabetic macular oedema

#### **Interventions**

- 1. Intravitreal injection of tiamcinolone
- 2. Placebo

As of March 2008: trial abandoned due to poor recruitment.

#### **Intervention Type**

Drug

#### **Phase**

**Not Specified** 

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

Triamcinolone

#### Primary outcome(s)

Pre-injection and then month 1, 3 and 6

- 1. Best corrected visual acuity (logarithm of the minimum angle of resolution [logMAR]) at each visit. A change in either direction of 10 letters on the logMAR chart would be considered significant
- 2. Near vision tested with a standard add on each visit, with time taken to read the standard N paragraph and the number of mistakes made
- 3. Intra-ocular pressure at each visit measured by standard applanation tonometry

## Key secondary outcome(s))

## Not provided at time of registration

## Completion date

01/07/2006

## Reason abandoned (if study stopped)

Lack of staff/facilities/resources

# **Eligibility**

## Key inclusion criteria

Not provided at time of registration

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

## Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

28/11/2003

#### Date of final enrolment

01/07/2006

## Locations

#### Countries of recruitment

United Kingdom

England

## Study participating centre

**B Floor** 

Nottingham United Kingdom NG7 2UH

# Sponsor information

## Organisation

Department of Health

# Funder(s)

## Funder type

Government

#### Funder Name

Queen's Medical Centre University Hospital NHS Trust (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration