ISRCTN90614292 https://doi.org/10.1186/ISRCTN90614292

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

Submission date 30/09/2004	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Stopped	
Last Edited 13/04/2011	**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
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

Primary study design
Interventional

Study design
Randomised controlled trial

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