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

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	Stopped	[ ] Protocol
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
28/11/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
B Floor
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Queen's Medical Centre University Hospital NHS Trust (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