

Perioperative intravitreal triamcinolone in phacoemulsification for concurrent clinically significant diabetic macular oedema

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/02/2018	Condition category 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
Mr Roger Wong

Contact details
Moorfields Eye Hospital
162 City Road
London
United Kingdom
EC1V 2PD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0141187727

Study information

Scientific Title

Perioperative intravitreal triamcinolone in phacoemulsification for concurrent clinically significant diabetic macular oedema

Study objectives

Does triamcinolone injected into the eye at the end of cataract surgery improve visual outcome for diabetic patients who have swelling of the retina at the time of cataract surgery?

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

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Eye Diseases: Diabetic macular oedema

Interventions

Triamcinolone vs no triamcinolone

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

triamcinolone

Primary outcome measure

Macular oedema at 1 year

Secondary outcome measures

1. Visual acuity at 1 year
2. Macular thickness/volume
3. Retinopathy progression
4. Capsular opacification
5. Macular ischaemia

Overall study start date

28/02/2007

Completion date

31/08/2008

Eligibility

Key inclusion criteria

1. Patients with Diabetic Mellitus, Type 1 or 2 Eligible
2. Patients with cataract sufficient in an eye to cause visual symptoms
3. Patients who have persistent CSME despite previous laser treatment
4. Patients who have moderate or severe NPDR and treated PDR as defined by a clinical modification of the Early Treatment Diabetic Retinopathy Study (ETDRS) retinopathy scale
5. OCT measurements of <300 micron at central subfield of foveal macula map

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

56 (28 patients; 28 controls)

Key exclusion criteria

1. Patients with no CSME
2. High risk proliferative retinopathy as defined by the DRS 17
3. Diabetes associated with specific genetic conditions, induced by drugs, chemicals or endocrinopathies
4. Coexistent ocular disease
5. Coexistent disease likely to affect retinopathy progression, for example severe carotid occlusive disease
6. Patients with coexistent disease likely to respond poorly to side effects of intravitreal triamcinolone, including glaucoma, OHT, steroid responders
7. Prior intraocular surgery to either eye
8. Complicated cataract surgery

Date of first enrolment

28/02/2007

Date of final enrolment

31/08/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Moorfields Eye Hospital

London

United Kingdom

EC1V 2PD

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Moorfields Eye Hospital NHS Foundation Trust (UK), NHS R&D Support Funding

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