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

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 05/02/2018	**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

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 later treatment
4. Patients who have moderate or severs 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 subfold of fats 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 triamcinalone, 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
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SW1A 2NL
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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