

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
Registration date 28/09/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/02/2018	Condition category Eye Diseases	☐ Individual participant data ☐ 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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Macular oedema at 1 year

Key secondary outcome(s)

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

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 fovea macula map

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration