

Randomised clinical trial to determine the incidence of Cystoid Macular Oedema (CMO) after cataract surgery with Intraocular Cefuroxime.

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 06/01/2010	Condition category Surgery	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

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
N0084132811

Study information

Scientific Title

Study objectives

To evaluate the risk of toxicity by determining the incidence of Cystoid Macular Oedema (CMO) when intraocular Cefuroxime is used at the end of cataract surgery and comparing this incidence when it is not used.

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

Surgery: Cataract

Interventions

120 patients, aged above 50 years having cataract surgery, 60 of which will receive intraocular cefuroxime, and 60 of which will not receive intraocular cefuroxime.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cefuroxime

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/07/2004

Eligibility**Key inclusion criteria**

120 patients, aged above 50 years having cataract surgery.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

19/09/2003

Date of final enrolment

31/07/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hull & East Yorkshire Eye Hospital

Hull

United Kingdom

HU3 2JZ

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2005		Yes	No