ISRCTN13489716 https://doi.org/10.1186/ISRCTN13489716

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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
06/01/2010

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

Study design
Randomised controlled trial

Primary study design
Interventional

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