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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 06/01/2010	**Condition category** Surgery	

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

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/09/2003

Completion date
31/07/2004

Eligibility

Key inclusion criteria
120 patients, aged above 50 years having cataract surgery.

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
120

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
England

United Kingdom

Study participating centre

Hull & East Yorkshire Eye Hospital
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

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

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

Study outputs

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