

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2010	<b>Condition category</b> Surgery	<input type="checkbox"/> 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

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?
<a href="#">Results article</a>	results	01/06/2005		Yes	No