

Prevention of post-cataract surgery macula oedema with prophylactic ketorolac

Submission date 06/07/2008	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/07/2008	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/05/2016	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.2

Study information

Scientific Title

Prevention of pseudophakic cystoid macula oedema with pre- and post-operative ketorolac

Study objectives

To assess whether patients treated with ketorolac 3 days pre- and 3 weeks post-operatively in combination with post-operative steroid drops have a lower incidence of cystoid macula oedema (CMO) following cataract surgery than those receiving standard clinical care (pre-operative topical flurbiprofen 1 hour prior to surgery and post-operative steroid drops).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval pending as of 07/07/2008. London-Surrey Borders ethics committee will be meeting on 9th July 2008.

Study design

Single-blind randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cystoid macular oedema (CMO)

Interventions

1. Intervention: ketorolac eye drops (0.4%) - 1 eye drop 4 times a day for 3 days before the operation and 3 weeks after the operation
2. Control arm: usual clinical care - 1 drop of flurbiprofen eye drop 1 hour before surgery and Maxidex® eye drop three times a day for 3 weeks post-cataract surgery

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ketorolac

Primary outcome measure

Central macula thickness as measured on optical coherence tomography at baseline (prior to surgery), 1 month after surgery, 2 months after surgery and 3 months after surgery.

Secondary outcome measures

1. Logarithmic minimal angle of resolution (LogMAR) visual acuity
2. Contrast sensitivity
3. Adverse events

The secondary outcomes will be measured at baseline (prior to surgery), 1 month after surgery, 2 months after surgery and 3 months after surgery.

Overall study start date

12/07/2008

Completion date

12/10/2009

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

1. Patients undergoing routine cataract surgery without an additional procedure
2. Patients with risk factors for developing CMO, such as pre-existing diabetes
3. Aged 18 to 75 years, male and female

Patients with epiretinal membranes or age-related macular degeneration (ARMD) will be analysed separately.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

1400

Key exclusion criteria

1. Patients who have previously had a reaction to ketorolac
2. Patients who are on systemic non-steroidal anti-inflammatories or steroids

Date of first enrolment

12/07/2008

Date of final enrolment

12/10/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Frimley Park Hospital NHS Foundation Trust

Frimley

United Kingdom

GU16 7UJ

Sponsor information

Organisation

Frimley Park Hospital NHS Foundation Trust (UK)

Sponsor details

Portsmouth Road

Frimley

England

United Kingdom

GU16 7UJ

Sponsor type

Hospital/treatment centre

Website

<http://www.frimleypark.nhs.uk/>

ROR

<https://ror.org/00mrq3p58>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Frimley Park Hospital NHS Foundation Trust (UK) - Ophthalmology Research Funding will cover any extra costs incurred

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