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Prevention of post-cataract surgery macula oedema with prophylactic ketorolac

Submission date 06/07/2008	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 22/07/2008	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 10/05/2016	**Condition category** Eye Diseases	[ ] Individual participant data [ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Frimley Park Hospital NHS Foundation Trust
Frimley
United Kingdom
GU16 7UJ

Sponsor information

Organisation
Frimley Park Hospital NHS Foundation Trust (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration