

Nepafenac and prevention of cystoid macular edema (CME) after cataract surgery in patients receiving latanoprost

Submission date 14/12/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/12/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/12/2010	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

Protocol serial number
N/A

Study information

Scientific Title

Nepafenac and prevention of cystoid macular edema (CME) after cataract surgery in patients receiving latanoprost: a randomised controlled trial

Study objectives

To evaluate whether there is a potential benefit, in term of cystoid macular edema (CME) prevention, in the administration of nepafenac and/or discontinuation of latanoprost in patients receiving latanoprost undergoing uneventful cataract surgery by phacoemulsification and intraocular lens (IOL) implantation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board, Faculty of Medicine, Chulalongkorn University, approved on the 14th October 2010 (ref: COA no.514/2010 IRB no.241/53)

Study design

Randomised double-masked controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cystoid macular edema (CME)

Interventions

Only eyes received 0.005% Latanoprost at least 1-month prior to a planned phacoemulsification with PC-IOL implantation, would be included, as indicated in the inclusion criteria. Subjects that were met with inclusion and exclusion criteria will be randomly assigned using block-of-six to one of the following three groups:

Group 1: 0.005% Latanoprost ed

Group 2: 0.005% Latanoprost ed and 0.1% Nepafenac ed

Group 3: artificial tears as Latanoprost placebo

0.005% Latanoprost and Latanoprost placebo are masked and given once daily before bedtime, starting from the first day after cataract surgery until the study endpoint at the 10th post-operative week. 0.1% Nepafenac (Nevanac; Alcon Inc., Fort Worth, Tx, USA) is given 3 times daily 3 days before surgery until the 3rd post-operative week.

All subjects undergo a clear corneal incision, phacoemulsification, and intraocular lens implantation using an acrylic foldable IOL (AcrysofIQ; Alcon Inc., Fort Worth, Tx, USA). Post-operative regimen includes 0.5% Moxifloxacin (Vigamox; Alcon Inc., Fort Worth, Tx, USA) given qid for 1 month, and 1% Prednisolone acetate (Pred-Forte; Allergan Inc., Westport, Ireland) given q2h x1d, qid x4wk then tid x4wk.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Nepafenac, latanoprost

Primary outcome(s)

Difference in incidence of post-operative CME - detected with OCT and measured up to 10 weeks accumulatively - between either approaches: discontinuation of Latanoprost or continuing Latanoprost but with the administration of Nepafenac, compared with a group of patients who continue to use Latanoprost as previously used pre-operatively (control group or non-intervention group).

Key secondary outcome(s)

Occurrence of post-cataract surgery CME in the non-intervention group (control group) detected by OCT.

Completion date

30/09/2011

Eligibility**Key inclusion criteria**

1. Eyes receiving 0.005% Latanoprost at least 1-month prior to a planned phacoemulsification with PC-IOL implantation
2. Aged over 18 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. History of intra-ocular inflammation
2. Clinically significant macular edema (CSME), or macular oedema of any aetiology
3. Proliferative diabetic retinopathy
4. Retinitis pigmentosa
5. Prior vitreo-retinal surgery
6. Pregnancy
7. Known/suspicious allergy to non-steroidal anti-inflammatory drugs (NSAIDs)/prostaglandin

analogues

8. Physical/mental/intellectual disabilities preventing from understanding and complying to protocol

Date of first enrolment

01/01/2011

Date of final enrolment

30/09/2011

Locations

Countries of recruitment

Thailand

Study participating centre

Department of Ophthalmology

Bangkok

Thailand

10330

Sponsor information

Organisation

Chulalongkorn University (Thailand)

ROR

<https://ror.org/028wp3y58>

Funder(s)

Funder type

Charity

Funder Name

Glaucoma Research Fund (UK)

Funder Name

King Chulalongkorn Memorial Hospital (Thailand) - Department of Ophthalmology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration