ISRCTN38025852 https://doi.org/10.1186/ISRCTN38025852

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	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 22/12/2010	**Overall study status** Completed	
Last Edited 22/12/2010	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Supawat Trepatchayakorn

Contact details
Department of Ophthalmology
Faculty of Medicine
Chulalongkorn University
1873 Rama 4 Road
Pathumwan
Bangkok
Thailand
10330

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 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 measure
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).

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

Overall study start date
01/01/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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)

Sponsor details
Faculty of Medicine
1873 Rama 4 Road
Pathumwan
Bangkok
Thailand
10330
+66 (0)2 256 4963
apchula@hotmail.com

Sponsor type
Government

Website
http://161.200.98.10/english/index.php?option=com_frontpage&Itemid=1

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

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