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Comparison of treatment with the steroid anti-inflammatory loteprednol etabonate and the non-steroidal anti-inflammatory drug (NSAID) bromfenac after cataract surgery.

Submission date
26/03/2018

Recruitment status
No longer recruiting

Registration date
02/05/2018

Overall study status
Completed

Last Edited
07/11/2019

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
After cataract surgery, patients need to use eye drops to reduce inflammation of the eye. Suitable medicines include non-steroidal anti-inflammatory drugs (NSAIDs) and steroids and they can be applied alone or in combination. However, steroid eye drops can cause an increase in pressure inside the eye.
The aim of this study is to investigate if using the NSAID bromfenac after cataract surgery has reduced side effects compared with the steroid loteprednol etabonate. This is the first study where bromfenac is administered alone after phacoemulsification. In previous studies it was administered in combination with a steroid drug. Bromfenac is an effective anti-inflammatory after cataract surgery and could simplify the number of eye drops patients have to use. This might reduce costs and side effects.

Who can participate?
Patients aged 45-90 years with age-related cataract undergoing phacoemulsification cataract surgery with posterior chamber intraocular lens implantation, in which the lens is removed and replaced with an artificial lens.

What does this study involve?
All participants will use ofloxacin (an antibiotic) as eye drops for 10 days after the operation. Patients in Group I will use bromfenac eye drops 2 times a day for 30 days after the operation. Patients in Group II will use loteprednol etabonate eye drops 4 times daily for 30 days after the operation.

What are possible benefits and risks of participating?
There are no known side-effects of bromfenac administered after phacoemulsification. Both drugs are approved by medicine regulatory bodies. There was no risk of participating in this study.

Where is the study run from?
There are two medical centers taking part in this study. The lead center is Department of Ophthalmology, Norbert Barlicki Memorial Teaching Hospital No. 1, Medical University of Lodz, Poland. Head: Wojciech Omulecki MD, PhD. The second center is Department of Ophthalmology and Visual Rehabilitation, Central Veterans Hospital in Lodz. Medical University of Lodz, Poland Head: Piotr Jurowski MD, PhD

When is study starting and how long is it expected to run for?
The start date was 5/05/2012 and the trial ran until 30/11/2014

Who is funding the study?
The study funder is Department of Ophthalmology, Norbert Barlicki Memorial Teaching Hospital No. 1, Medical University of Lodz, Poland and this department will be paying the costs that trial will incur during its lifecycle.

Who is the main contact?
Magdalena Kucharczyk-Pospiech, kucharczykma@gmail.com.

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Comparison of efficacy and safety of postoperative treatment with loteprednol etabonate and bromfenac after phacoemulsification

Study objectives
We hypothesise that there will be no difference in postoperative treatment with loteprednol etabonate and bromfenac after phacoemulsification

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Medical University of Lodz, 18/09/2012, RNN/164/12/KE.

Study design
Prospective case series

Primary study design
Observational

Secondary study design
Case series

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
Cataract surgery

Interventions
All patients used topical ofloxacin 4 times daily for 10 days postoperatively with an addition of the respective topical anti-inflammatory drug. The patients were randomized into 2 groups. Patients in Group I used a non-steroidal anti-inflammatory drug (0.09% bromfenac) 2 times daily for 30 days postoperatively. Patients in Group II used a steroidal anti-inflammatory drug (0.5% loteprednol etabonate) 4 times daily for 30 days postoperatively. Consecutive 58 patients (58 eyes) were randomly assigned to the one of the study groups regarding postoperative treatment. The follow-up examinations were performed on the first day and 1, 4, and 12 weeks postoperatively.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
bromfenac, loteprednol etabonate

Primary outcome measure
Intraocular inflammation assessed by laser flare photometry using Kowa FM -600 (Kowa Co. Ltd). Seven laser flare photometry measurements with values greater than 0 and which backgrounds differed less than 15% were saved. For all patients the highest and the lowest values of flare were excluded, according to the manufacturer's guidelines. The remaining 5 measurements were averaged. All measurements were taken with undilated pupils.
The follow-up examinations were performed on the first day and 1, 4, and 12 weeks postoperatively. Measurements were done at the same time of the day on scheduled visits.

Secondary outcome measures
1. Best corrected visual acuity (BCVA) on the Snellen chart
2. Intraocular pressure
3. Anterior and posterior segment evaluation
4. Foveal retina thickness using Optical Coherence Tomography (Topcon 3D OCT-1000 Mark II and Zeiss Stratus OCT Version 4.0.5 (0076)
5. Endothelial cell density measured with Tomey EM-3000 and Topcon SP 2000P Confocal Microscope
The follow-up examinations were performed on the first day and 1, 4, and 12 weeks postoperatively. Measurements were done at the same time of the day on scheduled visits.

Overall study start date
05/05/2012

Completion date
30/11/2014

Eligibility

Key inclusion criteria
1. Patients with age-related cataract undergoing phacoemulsification with posterior chamber intraocular lens (PC IOL) implantation. Patients having uneventful phacoemulsification with PC IOL implantation were enrolled.
2. BCVA between 0.1 and 0.5
3. Cataract nuclear sclerosis in the range between II and III according to LOCS III scale
4. No anti-inflammatory medication for 2 weeks prior to cataract surgery
5. No allergy to loteprednol etabonate (LE) or bromfenac
6. Aged 45-90 years

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
58

Total final enrolment
58

Key exclusion criteria
Patients with ocular infection, glaucoma, uveitis, diabetes, pseudoexfoliation syndrome, prior ocular trauma or intraocular surgery, corneal diseases, ocular tumors, optic nerve atrophy, autoimmune diseases, endocrine, renal, neurological, psychiatric disorders were excluded from the study.

Date of first enrolment
02/11/2013

Date of final enrolment
30/10/2014

Locations

Countries of recruitment
Poland

Study participating centre
Department of Ophthalmology, Norbert Barlicki Memorial Teaching Hospital No. 1, Medical University of Lodz, Poland Head: Wojciech Omulecki MD, PhD
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Study participating centre
Department of Ophthalmology and Visual Rehabilitation, Central Veterans Hospital, Medical University of Lodz, Poland Head: Piotr Jurowski MD, PhD
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Sponsor information

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Department of Ophthalmology, Norbert Barlicki Memorial Teaching Hospital No. 1, Medical University of Lodz

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Sponsor type
University/education

ROR
https://ror.org/02t4ekc95

Funder(s)

Funder type
Not defined

Funder Name
Medical University of Lodz

Results and Publications

Publication and dissemination plan
Results were submitted for publication by April 2018.

Intention to publish date
31/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because we did not receive agreement from our patients to share the data with other institutions.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2019	07/11/2019	Yes	No