Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The role of topical NSAIDs on inflammation and anterior segment complications after cataract surgery in patients with pseudoexfoliation syndrome

Protocol summary

Study aim

To study the antinfiammatory effect of topical NSAID as an adjunct topical steroid versus a topical steroid alone in patients with pseudo exfoliation (PEX) syndrome after cataract surgery.

Design

Patients who have a significant cataract with PEX and are candidate for phaco surgery will be randomly (random block) devided into 2 groups of 46 subjects with a single-blind allocation. Group 1: Patients who receive corticosteroid and antibiotic eye drops will also receive the ketorolac eye drop every 6 hours for 2 weeks. Group 2: Patients receiving betamethasone eye drops every 4 hours and chlobiotic every 6 hours.

Settings and conduct

The study will be done in eye clinic of Amiralmomenin Hospital in Rasht. In this study only patients will be blind. Addition of ketorolac eye drop will not be explained to the patients .

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients diagnosed with significant cataracts (Grade 3 and above) who have pseudoexfoliation in slit lamp examination; - Patients who have not used oral, topical or inhaled NSAIDs for a week before surgery; - Patients who have not used topical, inhaled, or systemic corticosteroids for 15 days before surgery; - Patients who have known hypersensitivity to any component of the NSAIDs; Non-inclusion criteria: - Patients with a history of uncontrolled chronic ocular or systemic disease; a history of ocular inflammation and trauma in the eye under study; - Intraoperative complications such as rupture of posterior capsule and vitreous loss during cataract surgery; - Patients with cataract surgery using either extracapsular cataract extraction or intracapsular cataract extraction method; - Patients with extensive postoperative ocular inflammation who need systemic anti-inflammatory drugs;

Intervention groups

Group 1 (Interventional Group): In addition to routine care (chloramphenicol eye drops every 6 hours and betamethasone eye drops every 4 hours until a one month after surgery), ketorolac (Sinarolac 0.5%) is taken every 6 hours for 15 days. Group 2 (Control Group): Patients who receive routine care including chloramphenicol eye drops every 6 hours and betamethasone eye drops every 4 hours until one month after surgery.

Main outcome variables

anterior chamber inflammation grade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160919029871N3**
Registration date: **2018-03-02, 1396/12/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-02, 1396/12/11**
Update count: **0**

Registration date

2018-03-02, 1396/12/11

Registrant information

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Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The role of topical NSAIDs on inflammation and anterior segment complications after cataract surgery in patients with pseudoexfoliation syndrome

Public title
Topical nonsteroidal anti-inflammatory drug effect on patients with pseudoexfoliation syndrome during cataract surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having Significant cataract (grade 3 and higher) and clinical signs of PEX. The patient should not be used systemic or inhaled NSAIDs within 1 week before surgery and the patients should not use the inhaled or systemic corticosteroids within 15 days after surgery
Exclusion criteria:
Having known hypersensitivity to any components of the NSAIDs uncontrolled chronic ocular or systemic inflammatory disease; a history of eye trauma and any retinal and macular disease, any intraocular complication during surgery (vitreous loss) The patient who must be treated with systemic anti-inflammatory medications for extensive inflammation following cataract surgery
Age
From **40 years** old to **95 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with cataract and clinical signs of PEX are randomly assigned into 2 groups through block randomization using blocks of size 4. Group 1: all medication in group 1 plus eye drop Ketorolac every 6 hours until 2 weeks. Group 2: Betamethasone eye drops every 4 hours and Chlobiotic every 6 hours
Blinding (investigator's opinion)
Single blinded
Blinding description
Addition of ketorolac eye drops will not be explained to the patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committe of Guilan University of Medical Sciences
Street address
Eye Research Center,Amiralmomenin Hospital, 17 Shahrivar st,Rasht
City
Rasht
Province
Guilan
Postal code
41396-37459
Approval date
2017-12-31, 1396/10/10
Ethics committee reference number
IR.GUMS.REC.1396.415

Health conditions studied

1

Description of health condition studied
Anterior segment inflammation and complications after cataract surgery in patients with pseudoexfoliation syndrome
ICD-10 code
H25
ICD-10 code description
Age-related cataract

Primary outcomes

1

Description
Percentage of subjects with anterior chamber inflammation based on cell count (CELL) and percentage of subjects with anterior chamber inflammation based on protein content based on the rating of the San-working Group (0 to 4 degrees).
Timepoint
1, 3, 7 and 30 days after surgery
Method of measurement

Clinical examination

Secondary outcomes

1

Description
The degree of opacity of the anterior capsule (ACO) (grade 0-4) and degree of opacity of the posterior capsule (PCO) (grade 0-4).
Timepoint
1,3,6 months postoperatively
Method of measurement
photo slit examination

Intervention groups

1

Description
Interventional Group: In addition to routine care including chloramphenicol eye drops every 6 hours and betamethasone eye drops every 4 hours until one month after surgery, ketorolac (Sinarolac 0.5%) is taken every 6 hours for 15 days.
Category
Treatment - Drugs

2

Description
Control Group: Patients who receive routine care including chloramphenicol eye drops every 6 hours and betamethasone eye drops every 4 hours until one month after surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Mitra Akbari
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Eye Research Center, Amiralmomenin Hospital,17 Shahrivar St,Rasht
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr Mitra Akbari
Position
Associate professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available