

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 antiinflammatory 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) divided 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 Amiralмомenin 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

Name

Mita Akbari

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

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

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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

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Mitra Akbari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Shila Kianmehr

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Health Service Management

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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