

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparing the effect of pre-operative doses of betamethasone acetate 0.1% and placebo on control of eye inflammation and pain after cataract surgery in patients who undergo phacoemulsification surgery.

Protocol summary

Study aim

Comparing the effect of pre-operative doses of betamethasone acetate 0.1% and placebo on control of ocular inflammation and pain after cataract surgery.

Design

randomized; double blinded clinical trial with control group; 40 patient in each group; paralell groups.

Settings and conduct

In this clinical trial study, 62 patients with senile cataract who need surgery; that referring to Mashhad Khatam-al-Anbia Hospital were randomly divided into two groups of 31 patients, A and B, 3 days prior to surgery untill the surgical day, in group A, betamethasone 0.1% eye drop and in group B, normal saline 0.9% will be administered 4 times a day, one drop each time. In this double-blind study, without the knowledge of researchers and patients of the drops, was completed by a pharmacologist's colleague and was named A and B. Eye inflammation and eye pain will be assessed before surgery and one, 7and 30 days after surgery.

Participants/Inclusion and exclusion criteria

inclusion criteria: patients with senile cataract which needed surgery. exclusion criteria: patients with significant superfacial eye disease; systemic rheumatologic disease; diabetes; using of medicine that cause dry eye and history of long term using of topical eye medicine like glaucoma.

Intervention groups

Prescribing pre-operative doses of betamethasone acetate 0.1% (intervention group) and normal saline 0.9% (control group) 4 times a day from 3 days prior to cataract surgery.

Main outcome variables

Ocular pain after cataract surgery; Ocular inflammation after cataract surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180606039989N1**

Registration date: **2018-07-27, 1397/05/05**

Registration timing: **retrospective**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

2018-07-27, 1397/05/05

Registrant information

Name

Fatemeh Zare malek abad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3257 1467

Email address

zaremf891@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2018-07-11, 1397/04/20

Trial completion date

empty

Scientific title

Comparing the effect of pre-operative doses of betamethasone acetate 0.1% and placebo on control of eye inflammation and pain after cataract surgery in patients who undergo phacoemulsification surgery.

Public title

Effect of pre-operative doses of betamethasone acetate 0.1% on control of eye inflammation and pain after cataract surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with senile cataract which needed surgery

Exclusion criteria:

Patient with significant superficial eye disease. Patient with systemic rheumatologic disease. Diabetic patient. Use of medicines which cause dry eye. History of long term use of topical eye drops like glaucoma medicines.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method was used to allocate patients to the control and experimental groups. At the beginning of the study, patients were assigned serial numbers 1-80, then the numbers were poured into a container and 40 items were randomly assigned that was placed in the experimental group and the remaining numbers were in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted as double-blind. The drops will be filled by pharmacologist colleague and without the knowledge of the researchers and patients, and will be named as A or B. After performing all the steps and follow-up, at the end of the design, the type of each drop will be revealed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mashhad University of Medical Sciences

Street address

Medical faculty, Pardis of university, Azadi sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

917751364

Approval date

2016-02-17, 1394/11/28

Ethics committee reference number

JR.MUMS.sm.REC.1394.620

Health conditions studied

1

Description of health condition studied

senile cataract

ICD-10 code

H25.0

ICD-10 code description

senile cataract

Primary outcomes

1

Description

Cell & Flare

Timepoint

before intervention, 1, 7, 30 days after intervention

Method of measurement

slit lamp biomicroscopy

2

Description

Ocular pain score

Timepoint

Before intervention, 1, 7, 30 days after intervention

Method of measurement

Ocular pain score in Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: administering betamethasone 0.1% eye drop 3 days prior to surgery 4 times a day, one drop each time.

Category

Prevention

2

Description

Control group: administering normal saline 0.9% eye drop 3 days prior to surgery 4 times a day, one drop each time.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al Anbia Hospital

Full name of responsible person

Fatemeh Zare Malek Abad

Street address

NO15, Alimardani35 Bhv., Salman12Ave.

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Email

zaremf891@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University Of Medical sciences; Daneshgah St.

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vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Zare Malek Abad

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available