Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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 asessed 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; useing of medicine that cause dry eye and history of long term useing 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 superfacial 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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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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91778-99191
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+98 51 3841 3007
Email
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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Person responsible for updating data

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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