

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study the effect of pre-operative doses of betamethasone acetate 0.1% on dry eye control and visual acuity after cataract surgery in patients referring to Khatam-al-Anbia hospital in 2016-2017

Protocol summary

Summary

Cataract is one of the main causes of visual impairment and blindness in the world and dry eye and visual impairment occur after cataract surgery. The aim of this study is to compare the effects of pre-operative doses of betamethasone acetate 0.1% and placebo on controlling dry eye and improvement of visual acuity after cataract surgery. In this clinical trial study 62 patients being candidate for cataract surgery were divided into two groups of 31 patients. Drops of A or B were administered 4 times a day. These drops contained either betamethasone 0.1% or normal saline. Postoperative follow up was performed on days 1, 7 and one month after surgery. Dry eyes symptoms were evaluated by the OSDI questionnaire, Schirmer and TBUT test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017103037105N1**

Registration date: **2017-11-10, 1396/08/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-10, 1396/08/19

Registrant information

Name

Seyedeh Zeinab Hashemi Javaheri

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3608 2257

Email address

hashemiz891@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-11-04, 1395/08/14

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of pre-operative doses of betamethasone acetate 0.1% on dry eye control and visual acuity after cataract surgery in patients referring to Khatam-al-Anbia hospital in 2016-2017

Public title

Study the effect of pre-operative doses of betamethasone acetate 0.1% on dry eye control and visual acuity after cataract surgery in patients referring to Khatam-al-Anbia hospital in 2016-2017

Purpose

Prevention

Inclusion/Exclusion criteria

Criteria for entering the study: age-related cataract; requiring ophthalmic surgery for cataract surgery. Exit criteria: significant eye disease; systemic rheumatologic diseases, and diabetes; the use of drowsiness drugs; long history of long-term eye drops such as glaucoma drugs and the complications of cataract surgery during

or after from surgery.

Age

From **40 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Vakilabad Blvd.

City

Mashhad

Postal code

Approval date

2016-06-22, 1395/04/02

Ethics committee reference number

IR.MUMS.SM.REC.1395.76

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H26.9

ICD-10 code description

Cataract, unspecified

Primary outcomes

1

Description

Eye dryness

Timepoint

Before surgery and 1, 7, 30 days after surgery

Method of measurement

OSDI questionnaire was filled by patients and Shirmer test was performed with Schirmer paper, TBUT test was performed with slit lamp, BCVA measured by optometrist

Secondary outcomes

empty

Intervention groups

1

Description

Control group: normal saline 0.9% was prescribed 3 days before the date considered for surgery, with the frequency 4 times a day and every time a drop in the desired eye

Category

Placebo

2

Description

Intervention group: betamethasone acetate 0.1% was prescribed 3 days before the date considered for surgery, with the frequency 4 times a day and every time a drop in the desired eye

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-al-Anbia hospital

Full name of responsible person

Street address

Khatam-al-Anbia hospital, Shahid Gharani Blvd.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Saeed Shokoohirad

Street address

Mashhad University of Medical Sciences, Daneshgah St.

City

Mashhad

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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty