Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of tacrolimus 0.03% drop and artificial tear drop on the amount of tear production in patients with dry eye after cataract surgery with phacoemulsification method.

Protocol summary

Summary

Purpose of study: Comparing the effect of tacrolimus 0.03% drop and artificial tear drop on dry eye after cataract surgery. Design of study: Randomized double blind clinical trial. Method: The study will perform on patients referring to Shahid Sadoughi Hospital in Yazd. Main Inclusion criteria include patients aged above 50 years old with cataract planned for phacoemulsification. Main Exclusion criteria include diagnosis of dry eye syndrome by Schirmer 1 test <10 mm or tear film break up time <10 seconds; any history of inflammatory or infectious ocular disease; history of any prior ocular surgery; and history of any medication or condition which may induce dry eye. The patients will undergo cataract surgery. 1 week after surgery, Schirmer 1 test, tear breakup time, and Ocular Surface Disease Index would be evaluated for diagnosing new onset dry eye. 60 eyes with diagnosis of dry eye after cataract surgery, depend on the randomized code for each patient taken by the clinic staff, would undergo treatment with tacrolimus 0.03% drop every 12 hours or artificial tear drop every 6 hours. After 1 month, Schirmer 1 test, tear breakup time, and Ocular Surface Disease Index would be evaluated again by another examiner who does not know the results and groups. Then the results would be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102430485N1**
Registration date: **2017-03-27, 1396/01/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-27, 1396/01/07

Registrant information

Name

Armin Hemati

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yazd University of Medical Sciences

Expected recruitment start date

2016-10-29, 1395/08/08

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of tacrolimus 0.03% drop and artificial tear drop on the amount of tear production in patients with dry eye after cataract surgery with phacoemulsification method.

Public title

Impact of tacrolimus 0.03% eye drop on dry eye symptoms

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients aged above 50 years old with cataract planned for phacoemulsification. Exclusion criteria: history of an ocular trauma or any chemical or thermal burn; allergy to any of the study medications; history of any condition that may cause dry eye; systemic connective tissue disease; corneal contact lens wear; any active ocular disease; uncontrolled systemic disease; a history of ocular allergic disease; prior refractive surgery or any ocular surgery; history of any medication which may induce dry eye; any history of inflammatory or infectious ocular disease; diagnosis of dry eye syndrome by Schirmer 1 test <10 mm or tear film break up time <10 seconds.
Age
From **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
With the SAS software, a number for each patient was reserved with a randomization code that was corresponding with that number.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yazd University of Medical Sciences
Street address
Yazd University of Medical Sciences, boulevard of Daneshgah, Yazd
City
Yazd
Postal code
8915173143
Approval date
2016-01-06, 1394/10/16
Ethics committee reference number
IR.SSU.MEDICINE.REC.1394.370

Health conditions studied

1

Description of health condition studied
dry eye syndrome
ICD-10 code
H04.1
ICD-10 code description
Other disorders of lacrimal gland

Primary outcomes

1

Description
Eye problems in doing daily jobs
Timepoint
Before intervention and one month after treatment
Method of measurement
Ocular Surface Disease Index questionnaire

2

Description
Tear break up time
Timepoint
Before intervention and one month after treatment
Method of measurement
In seconds, With timer and Slit Lamp

3

Description
Tear production
Timepoint
Before intervention and one month after treatment
Method of measurement
Schirmer 1 test in millimeters

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first patient with a unique code (1) would be given package A (include tacrolimus 0.03% drop). Patients would instil tacrolimus 0.03% drop every 12 hours a day for one month. Patients would continue this treatment for one month and return for examination afterwards.
Category
Treatment - Drugs

2

Description
Control group: The second patient with a unique code (2) would be given package B (include artificial tear drop). Patients would instil a drop of artificial tear drop, with trademark of Artelac, in eye every 6 hours and would continue for 1 month. After 1 month they would return for examination.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baghaeepour clinic

Full name of responsible person
Armin Hemati (medical doctor, ophthalmology resident)

Street address
Ophthalmology clinic, Baghaeepour clinic, Shahid Sadoughi hospital, boulevard of Shahid Ghandi, Yazd

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Yazd University of Medical Sciences

Full name of responsible person
Amirhoushang Mehrparvar

Street address
Yazd University of Medical Sciences, boulevard of Daneshgah, Yazd

City
Yazd

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for research of Yazd 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

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Armin Hemati

Position
Ophthalmology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position
Ophthalmologist

Other areas of specialty/work

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Person responsible for updating data

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Position
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Other areas of specialty/work

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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