

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

2017-03-27, 1396/01/07

##### 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 breakup 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

##### Registrant information

###### Name

Armin Hemati

###### Name of organization / entity

Yazd University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3822 4002

###### Email address

m.mahdavi@ssu.ac.ir

##### 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 instill 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**

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**Grant code / Reference number**

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**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****Street address**

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armin7hemati@gmail.com

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

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Manjie Mahdavi

**Position**

Ophthalmologist

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## Person responsible for updating data

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**Web page address**

**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*