

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Clinical trial comparing the effects of Tea Tree Oil and artificial tear and betamethasone drops on dry eye symptoms after phacoemulsification cataract surgery

#### Protocol summary

##### Summary

This study is a clinical trial and be carried on in Farabi Ophthalmology Center that examine the dry-eye symptoms following a Phacoemulsification Cataract Surgery. The volunteers fill the Ocular Surface Disease questionnaire, and they are selected if: (1) Dry-eye symptoms following Phacoemulsification Cataract Surgery that have not improved after 1 month with conventional treatments(2) The questionnaire index is equal or more than 30. The patients are excluded if they have historic eye surgeries or diseases that cause dry eye. We will record all the relevant information from the acuity vision and Tear osmolarity testing and microscopic demodex examinations. In this study we investigate 60 eyes of 60 patients. The selected volunteers are randomly divided in two groups: (A) trial and (B) control. The control group takes Artificial Tear and betamethasone 0.1% drop and eyelid washing with eyesol shampoo without TTO every 8 hours a day for one month and the trial group takes Artificial Tear and betamethasone drop in the same way as control group as well as eyesol shampoo with TTO 5%. After one months, we repeat all the above-mentioned tests and Ocular Surface Disease Index Questionnaire. We will then compare the results of these two groups. The main outcome of this study is to compare the effects of Tea Tree Oil and artificial tear and betamethasone drops on dry eye symptoms after surgery, cataract Phacoemulsification method.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013111313567N5**

Registration date: **2015-06-21, 1394/03/31**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-06-21, 1394/03/31

##### Registrant information

###### Name

Mehrdad Mohammadpour

###### Name of organization / entity

Tehran university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5542 6286

###### Email address

mohammadpour\_m@sina.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2015-06-15, 1394/03/25

##### Expected recruitment end date

2015-08-16, 1394/05/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial comparing the effects of Tea Tree Oil and artificial tear and betamethasone drops on dry eye symptoms after phacoemulsification cataract surgery

##### Public title

Impact of Tea Tree Oil on dry eye treatment

## Purpose

Treatment

## Inclusion/Exclusion criteria

The Inclusion criteria: Dry-eye symptoms following Phacoemulsification Cataract Surgery that have not improved after 1 month with conventional treatments (artificial tear and betamethasone 0.1% drops); Index of 30 or more from the Ocular Surface Disease Questionnaire; The Schirmer test of 10 millimeter or less; The Tear Break up Times of 7 seconds or less; Lack of eye trauma; The absence of uveitis. Exclusion criteria: Surgery on eyes including Surgical Correction of Refractive Errors; Using contact lenses; Systemic diseases which cause dry eye such as Sjogren, Diabetic Retinopathy and end organ damage disease

## Age

No age limit

## 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

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

##### Street address

Central Organization of University, Qods Ave., Keshavarz Blvd., Valiasr Squ. Tehran .Iran

##### City

Tehran

##### Postal code

#### Approval date

2015-05-11, 1394/02/21

#### Ethics committee reference number

93-04-30-27770-148038

## 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

Moisture eye

#### Timepoint

Before intervention-one month after treatment

#### Method of measurement

Schirmer Test -Millimeters

### 2

#### Description

Eye problems in performing daily

#### Timepoint

Before intervention-one month after treatment

#### Method of measurement

Ocular Surface Disease Index Questionnaire

### 3

#### Description

Tear break up time

#### Timepoint

Before intervention-one month after treatment

#### Method of measurement

Measured in seconds -With timer and Slit Lamp

### 4

#### Description

Visual acuity

#### Timepoint

Before intervention-one month after treatment

#### Method of measurement

Snellen chart

### 5

#### Description

The number of demodex of 4 eyelashes of each eye

#### Timepoint

Before intervention-one month after treatment

#### Method of measurement

Microscopic demodex examination

### 6

#### Description

Tear Osmolarity

#### Timepoint

Before intervention-one month after treatment

#### Method of measurement

Tearlab osmometer

#### Secondary outcomes

empty

#### Intervention groups

##### 1

#### Description

Intervention group: The first patient with a unique code (1) be given package A (i.e.Eyesol Ophthalmic cleansing shampoo containing Tea tree oil 5% plus Betamethasone Eye Drops 0.1% plus Artelac Eye Drops). Patients need to instil a drop of artificial Eye Drops, with trademark of Artelac, every 6 hours a day for one month. It contains 1.6 milligram (0.5 millilitre ) of artificial tears mainly hypromellose. In addition participants in the intervention group should instil a drop of Betamethasone Eye Drops 0.1% in the first week every 6 hours, the second week every 8 hours, the third week every 12 hours and the fourth week every 24 hours a day for one month. Betamethasone Eye Drops 0.1% with trademark of Betasonate is a product of Sina Darou. In addition participants in this group should scrub their eyelids every 8 hours with Eyesol Ophthalmic cleansing shampoo containing Tea tree oil 5%, Rewopol,Rewoteric ,HEC,PEG - 40 Hydrogenated castor oil produced in samin sirjan Co. under cooperative agreement with Dr. Straetmans Co. Germany. Volunteers 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) be given package B (i.e.Eyesol Ophthalmic cleansing shampoo without Tea tree oil plus Betamethasone Eye Drops 0.1% plus Artelac Eye Drops). Patients need to instil a drop of artificial Eye Drops, with trademark of Artelac, every 6 hours a day for one month. It contains 1.6 milligram (0.5 millilitre ) of artificial tears mainly hypromellose. In addition participants in the control group should instil a drop of Betamethasone Eye Drops 0.1% in the first week every 6 hours, the second week every 8 hours, the third week every 12 hours and the fourth week every 24 hours a day for one month. Betamethasone Eye Drops 0.1% with trademark of Betasonate is a product of Sina Darou. In addition participants in this group should scrub their eyelids every 8 hours with Eyesol Ophthalmic cleansing shampoo (without Tea tree oil) containing Rewopol,Rewoteric ,HEC,PEG - 40 Hydrogenated castor oil produced in samin sirjan Co. under cooperative agreement with Dr. Straetmans Co. Germany. Volunteers continue this treatment for one months and return for examination afterwards.

#### Category

Placebo

#### Recruitment centers

##### 1

#### Recruitment center

##### Name of recruitment center

Farabi Eye Center

##### Full name of responsible person

Mehrdad Mohammadpour

##### Street address

Farabi Hospital, Ghazvin square, South Kargr Avenue, Enghelab Square, Tehran, Iran.

##### City

Tehran

#### Sponsors / Funding sources

##### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

##### Full name of responsible person

Doctor Akbar Fotouhi

##### Street address

Seventh floor, Central Organization Building, Qods Ave., Keshavarz Blvd., Vali-e-Asr Square, Tehran, Iran.

##### City

Tehran

#### 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, Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Mehrdad Mohammadpour

##### Position

Associate Professor of Tehran University of Medical Sciences

**Other areas of specialty/work****Street address**

Eye Research Center, Farabi Hospital, Ghazvin Square, South Kargar Avenue, Enghelab Square, Tehran, Iran.

**City**

Tehran

**Postal code****Phone**

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**Fax****Email**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Eye Research Center, Farabi Hospital.

**Full name of responsible person**

Doctor Mehrdad Mohammadpour

**Position**

Anterior Segment and Cornea Fellowship

**Other areas of specialty/work****Street address**

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00

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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*