

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**Comparing the effect of green tea extract and artificial tear in control of clinical symptoms, tear production, tear film stability, health of ocular surface and meibomian gland in the patients with dry eye and meibomian gland dysfunction.**

### Protocol summary

#### Summary

Objectives: To evaluate the efficacy and safety of green tea extract in the treatment of the patients with meibomian gland dysfunction and dry eye. Design: Clinical Trial stage 2, Single Center, Randomized, double blinded, control with placebo. Setting and conduct: We will select Sixty patients with dry eye that will divide 2 group. Age will range from 30 to 70 years. In the first group, we will use artificial tear eye drops and in second group artificial tears plus green tea extract. All Patients will evaluate at the beginning and end of the study (one month later) for signs of dry eye, tear production, tear film stability, ocular surface and Meibomian glands health. Major inclusion criteria included: Dry eye and meibomian gland dysfunction. Major exclusion criteria included: Use of ophthalmic medication in one month before study, ocular surface disorders such as corneal surface damage, eyelid complications and previous ocular surgery. Intervention: In the first group, we will use artificial tear eye drops and in second group artificial tears plus green tea extract. Main outcome measures (variables): Signs of dry eye, tear production, tear film stability, ocular surface and Meibomian glands health.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2014042117374N1**  
Registration date: **2016-10-03, 1395/07/12**  
Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2016-10-03, 1395/07/12

#### Registrant information

##### Name

Mehdi Zadmehr

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1629 1779

##### Email address

zadmehr@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, shiraz university of medical sciences

#### Expected recruitment start date

2014-05-15, 1393/02/25

#### Expected recruitment end date

2014-07-21, 1393/04/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the effect of green tea extract and artificial tear in control of clinical symptoms, tear production, tear film stability, health of ocular surface and meibomian gland in the patients with dry eye and meibomian gland dysfunction.

#### Public title

Efficacy of green tea extract in the treatment of the patients with dry eye.

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria included: Dry eye and meibomian gland dysfunction. Exclusion criteria included: Use of oral tetracyclines and corticosteroids in 3 months before study and all ophthalmic medication in one month before, Patients with other ocular surface disorders such as corneal surface damage, eyelid complications except blepharitis, any previous ocular surgery, history of drug allergy in eye, use of ophthalmic medication to treat other ophthalmic complication except dry eye and blepharitis, severe blepharitis and dry eye that require systemic treatment, Nasolacrimal duct system disorders such as punctal occlusion, Pregnancy and lactation, as well as patients taking systemic medications and systemic diseases affecting this study are excluded.

## Age

From **30 years** old to **70 years** old

## Gender

Both

## Phase

2-3

## 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

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences Ethics committee

##### Street address

Central Building of the University, Across the flestin street, Zand street, Shiraz, Fars.

## City

Shiraz

## Postal code

7134997446

## Approval date

2014-01-28, 1392/11/08

## Ethics committee reference number

CT-P-92-5201

## Health conditions studied

### 1

#### Description of health condition studied

Dry eye

#### ICD-10 code

VII

#### ICD-10 code description

Diseases of the eye and adnexa

## Primary outcomes

### 1

#### Description

Clinical symptom

#### Timepoint

Before the intervention, one month after the intervention

#### Method of measurement

The questionnaire included: symptoms of itching, Burning, Reduced vision, Foreign body sensation, Pains, photophobia, Redness.

### 2

#### Description

Tear production

#### Timepoint

Before the intervention, one month after the intervention

#### Method of measurement

Shirmer test

### 3

#### Description

Tear film stability

#### Timepoint

Before the intervention, one month after the intervention

#### Method of measurement

Tear Film Break Up Time test

### 4

#### Description

Ocular surface health

#### Timepoint

Before the intervention, one month after the intervention

#### Method of measurement

Staining of the cornea and conjunctiva

## 5

### **Description**

Meibomian gland safety

### **Timepoint**

Before the intervention, one month after the intervention

### **Method of measurement**

Color and quality of gland secretion

## **Secondary outcomes**

### 1

#### **Description**

Drug allergy

#### **Timepoint**

Before the intervention, one month after the intervention

#### **Method of measurement**

Clinical symptom

### 2

#### **Description**

Eye infection

#### **Timepoint**

Before the intervention, one month after the intervention

#### **Method of measurement**

Clinical symptom

## **Intervention groups**

### 1

#### **Description**

Intervention group: Artificial tear eye drop, one drop, three times a day for one month+ Green tea eye drop, one drop, three times a day for one month. For preparation of green tea drop, we brewed green tea then add a good amount of protective substances Benzalkonium Chloride under sterile conditions, filtrated and autoclaved. Amount of protective substances obvious with preservative challenge test.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Standard treatment include artificial tear eye drop one drop three times a day for one month.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Poostchi Ophthalmology Clinic

##### **Full name of responsible person**

Mehdi Zadmehr Resident of ophthalmology

#### **Street address**

Opposite the school of Medicine, Shiraz, Zand street.

#### **City**

Shiraz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr basir hashemi

##### **Street address**

Central building of the University, Across the Flestin street, Zand street, Shiraz.

##### **City**

Shiraz

##### **Grant name**

طرح های پژوهشی دانشگاه

##### **Grant code / Reference number**

5201

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Mehdi Zadmehr

##### **Position**

Resident of ophthalmology

##### **Other areas of specialty/work**

##### **Street address**

Central building of the university, Across the Flestin street, Zand street, Shiraz.

##### **City**

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##### **Postal code**

7134814336

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+98 711230541019

##### **Fax**

+98 71 1212 2430

##### **Email**

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**Web page address**

<http://www.sums.ac.ir/>

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Mahmood Nejabat

**Position**

Anterior fellowship

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mehdi Zadmehr

**Position**

Resident of ophthalmology

**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*