

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)

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+98 71 1629 1779

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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

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Person responsible for scientific inquiries

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Shiraz University of Medical Sciences

Full name of responsible person

Dr Mahmood Nejabat

Position

Anterior fellowship

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Full name of responsible person

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Position

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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