Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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 incliusion 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
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Iran (Islamic Republic of)
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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

Incliusion 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 belepharitis 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 Brake 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 glangd 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

Contact

Name of organization / entity

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Full name of responsible person

Dr Mahmood Nejabat

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Anterior fellowship

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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