

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Tea tree oil effect on blepharitis-associated dry eye syndrome: a double-blind placebo control randomized clinical trial

Protocol summary

Study aim

The effect of tea tree oil on blepharitis-related dry eye syndrome is investigated.

Design

A clinical trial with control group, with parallel groups, double-blind, randomized, on 100 patients. Block randomization was used for randomization.

Settings and conduct

In this study, patients referred to the ophthalmology clinic of Firoozabadi, Rasoul Akram and Lolagar hospitals whom have the necessary conditions were included in the study and after performing the necessary tests and examinations, they were randomly received drugs or placebo in the control group or intervention. After 4 weeks, they are re-examined. The study is performed in a double-blind manner; throughout the study, researchers are unaware of the belonging of each drug and placebo to the groups, and patients will not be aware of the name of the drug received and its effects. Medication and placebo are prescribed by a doctor outside the research team.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with blepharitis or dry eye older than or equal to 18 years; ocular surface disease index score above 22, strip meniscometry tube test score equal or above 3 mm. Exclusion criteria include use of topical ocular treatments; receiving any systemic treatment now or during the past month that affects the tear secretion, contact lens use, recent ocular surgery; anterior segment active inflammation; pregnancy; lactation; any dermatological or systemic disease that affects the surface of the eye.

Intervention groups

The control group receives tea tree oil-free gel every 12 hours which is massaged on the eyelid for four weeks and the intervention group receives tea tree oil gel 5% for massage on the eyelid twice a day for four weeks.

Main outcome variables

Severity of blepharitis symptoms and signs; tear break-

up time, basal surface secretion of tear; corneal stippling; severity of dry eye symptoms and signs

General information

Reason for update

Acronym

TTT (Tea Tree Trial)

IRCT registration information

IRCT registration number: **IRCT20191230045954N1**

Registration date: **2021-04-02, 1400/01/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-02, 1400/01/13**

Update count: **0**

Registration date

2021-04-02, 1400/01/13

Registrant information

Name

Hamidreza Hasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3420 7972

Email address

hasani.hr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Tea tree oil effect on blepharitis-associated dry eye syndrome: a double-blind placebo control randomized clinical trial

Public title
Effect of tea tree oil on blepharitis-associated dry eye syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age older than or equal to 18 years Ocular Surface Disease Index(OSDI) test score greater than or equal to 22 Eyelid margin disease without severe inflammation Strip Meniscometry (SM) Tube test greater than or equal to 3-4 mm People who sign the informed consent form
Exclusion criteria:
People who are very old and difficult to get information from People who have received systemic treatment for eyelid disease at the time of admission or one month before admission Receive any systemic treatment now or during the past month that affects tear secretion People who wear contact lenses Recent ocular surgery (less than 3 months ago) Active disease in the anterior segment of the eyeball except dry eye (such as keratitis), Patients with HIV (human immunodeficiency virus), sarcoidosis, graft versus host disease with previous diagnosis Patients with rheumatic diseases, serious kidney disease (need for hemodialysis or history of kidney transplantation), diabetes, pregnancy, lactation, any dermatological or systemic disease that affects the surface of the eye known medication allergies to the drugs used in this study

Age
From **18 years** old to **99 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random allocation to be placed in the tea tree oil group or placebo to receive intervention at the standard time will be done using the permuted balance block randomization technique. According to this issue, the blocks considered in this study will be quadruple blocks. Using STATA software, a random number chain of

1 to 6 will be generated to reach the desired sample size. Considering that the total number of cases for receiving medicine in 4 blocks is 6, if the number produced is more than 6, the next number will be produced without considering it. Preparation of random assignment sequences of drug groups and placing them in sealed envelopes and numbering with a 5-digit serial number will be done by a third party who is not involved in the design of the study. All envelopes have a number The series will be 5 digits, which will be opened immediately after the patients enter the study, and the patients will be divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is performed in a double-blind manner. Throughout the study, researchers were unaware that each medication and placebo belonged to the group and patients will not be aware of the name of the Medication and its effects. Medication and placebo are prescribed by a doctor outside the research team.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-11-30, 1399/09/10

Ethics committee reference number

IR.IUMS.REC.1399.961

Health conditions studied

1

Description of health condition studied

Dry eye disease

ICD-10 code

H04.1

ICD-10 code description

Other disorders of lacrimal gland

2

Description of health condition studied

Blepharitis

ICD-10 code

H01.0

ICD-10 code description

Blepharitis

Primary outcomes

1

Description

Ocular Surface Disease Index (OSDI) questionnaire score

Timepoint

Measurement of OSDI questionnaire score at the beginning of the study (before the intervention) and 28 days after the start of the gel containing tea tree oil and placebo

Method of measurement

Fill out the questionnaire

2

Description

Tear break up test

Timepoint

Measurement of tear break up test at the beginning of the study (before the intervention) and 28 days after the start of the gel containing tea tree oil and placebo

Method of measurement

Using fluorescein moistened with saline solution, the average time elapsed before the initial dissolution of the tear is measured three times.

3

Description

The amount of tear basal secretion

Timepoint

Measurement of tear basal secretion at the beginning of the study (before the intervention) and 28 days after the start of the gel containing tea tree oil and placebo

Method of measurement

Strip Meniscometry Tube

4

Description

Corneal staining

Timepoint

Examination of corneal discoloration areas at the beginning of the study (before the intervention) and 28 days after the start of the gel containing tea tree oil and placebo

Method of measurement

By an ophthalmologist with a slit lamp and blue light to the cornea

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group received a gel containing 5% tea tree oil for massage on the eyelid twice a day for four weeks.

Category

Treatment - Other

2

Description

Control group: The control group receives tea tree oil-free gel every 12 hours (twice a day) which is massaged on the eyelid for four weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool-e-Akram hospital

Full name of responsible person

Hamidreza Hasani

Street address

Hazrate Rasool Akram Hospital, Niayesh St, Satarkhan Av, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 6435 1000

Email

hamidrezahasani@yahoo.com

2

Recruitment center

Name of recruitment center

Firoozabadi Hospital

Full name of responsible person

Hamidreza Hasani

Street address

Shahr-e-Rey Square-Fadaian-e-Islam St- Tehran

City

Tehran

Province

Tehran

Postal code

9411318497

Phone

+98 21 5104 8000

Email

hamidrezahasani@yahoo.com

3

Recruitment center

Name of recruitment center

Lolagar hospital

Full name of responsible person

Hamidreza Hasani

Street address

Between Azarbayjan and Dampezhski st - Khosh ave
- Tehran

City

Tehran

Province

Tehran

Postal code

4415913459

Phone

+98 21 6683 5000

Email

hamidrezahasani@yahoo.com

4

Recruitment center

Name of recruitment center

Alborz university of medical sciences

Full name of responsible person

Hamidreza Hasani

Street address

Jahanshahr blvd

City

Karaj

Province

Alborz

Postal code

1968655816

Phone

+98 21 8865 0450

Email

hamidrezahasani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hamidreza Hasani

Street address

Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan
Av, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 6435 1000

Email

hamidrezahasani@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hamidreza Hasani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan
Av, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 6435 1000

Email

hamidrezahasani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Hamidreza Hasani

Position

Assistant professor

Latest degree

Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Jahanshahr Blvd
City
Karaj
Province
Alborz
Postal code
3143744692
Phone
+98 21 8865 0450
Fax
Email
hamidrezahasani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hamidreza Hasani
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Hazrate Rasool Akram Hospital, Niayesh St, Satarkhan
Av, Tehran

City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 1000
Email
hamidrezahasani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available