

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Efficacy of EyeCalmin eye drop on inflammation of ocular surface

Protocol summary

Summary

To evaluate efficacy of green tea extract as EyeCalmin eye drop (Dinee company) on signs and symptoms of ocular surface irritation such as redness, pruritus, foreign body sensation and eyestrain. In this clinical trial 30 patients with ocular surface irritation were enrolled. They randomly received EyeCalmin eyedrop or placebo. Patients examined before the enrollment, then they take drugs four times a day for two weeks and the second examination was performed. After passing the time required for drug washout, the same patients received the alternate drug and examination with the same schedule was performed. The results of the two drugs compared in the same patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903234166N1**
Registration date: **2010-09-15, 1389/06/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-15, 1389/06/24

Registrant information

Name

Rana Daei Sorkhabi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1655 1332

Email address

rana@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Drug Applied Research Center

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2009-09-07, 1388/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of EyeCalmin eye drop on inflammation of ocular surface

Public title

Efficacy of green tea extract on ocular redness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.ocular redness 2.foreign body sensation 3.eyestrain 4.ocular allergy. Exclusion criteria: 1.any intraocular inflammation 2.any corneal disease 3.viral or bacterial infections 4.any drug induced side effects

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Drug Applied Research Center

Street address

Daneshgah avenue

City

Tabriz

Postal code**Approval date**

2009-02-10, 1387/11/22

Ethics committee reference number

2922/4/5

Health conditions studied**1****Description of health condition studied**

ocular surface irritation

ICD-10 code

H10.1

ICD-10 code description

Acute atopic conjunctivitis

Primary outcomes**1****Description**

foreign body sensation, redness, irritation, eye strain

Timepoint

2 weeks

Method of measurement

clinical exam

Secondary outcomes**1****Description**

tear film stability

Timepoint

2 weeks

Method of measurement

clinical exam

Intervention groups**1****Description**

eyecalmin 4 times a day for two weeks

Category

Treatment - Drugs

2**Description**

placebo 4 times a day for 2 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz university clinics

Full name of responsible person**Street address****City**

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Drug Applied Research Center

Full name of responsible person

Hossein Babaei

Street address

Educational Development Center

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Drug Applied Research Center

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

Tabriz universit of medacal sciences

Full name of responsible person

Rana Daei Sorkhabi

Position

Assistant professor

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

Tabriz Nikookari hospital

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Full name of responsible person

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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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