Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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.foriegn 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
forignn 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 Reaserch 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 Reaserch 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

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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