Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Randomized controlled trial for evaluation of safety and efficacy of topical cyclosporine 2% versus topical prednisolone for treatment of herpetic interstitial keratitis

Protocol summary

Summary

Objectives: To evaluate the efficacy of topical cyclosporine 2% for treatment of herpetic interstitial keratitis. Design: Prospective randomized controlled clinical trial, single center, single blinded to patients. Two arms of study will be 24 eyes of 24 patients in cyclosporine group and 24 eyes of 24 patients in conventional treatment group. Setting and conduct: Feiz hospital, Isfahan University of Medical Sciences. Patients who are allotted for treatment of herpetic interstitial keratitis will randomly assigned to conventional corticosteroid or cyclosporine groups while receiving standard prophylactic oral Acyclovir treatment. Subjects will be evaluated 2 and 4 weeks after initiation of treatment regarding corneal haziness and visual acuity. Participants: Patients with herpetic interstitial keratitis who are candidate to begin topical immunosuppressive therapy for treatment of the condition. Patients with history of treatment of the current condition with corticosteroids will not enter into the study. Intervention: Topical application of cyclosporine Main outcome measures: cornea haziness, visual acuity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052112724N2**
Registration date: **2015-10-28, 1394/08/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-28, 1394/08/06

Registrant information

Name

Alireza Peyman

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-05-31, 1394/03/10

Expected recruitment end date

2016-05-30, 1395/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized controlled trial for evaluation of safety and efficacy of topical cyclosporine 2% versus topical prednisolone for treatment of herpetic interstitial keratitis

Public title

Topical cyclosporine 2% for herpetic interstitial keratitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of herpetic interstitial keratitis, No history of treatment with any form of

immunosuppressant drugs one month before intervention, No history of diabetes mellitus, No history of co-existing viral disease. Exclusion criteria: Any side effect attributable to study, patients who have not used drugs regularly, patients who have not come for follow up visits.

Age
From **16 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Patients will be randomly assigned to intervention and control groups with a random allocation software program. The patients will not be aware of the content of coded drop bottles but the examiners will know about the type of delivered drops.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezarjerib St.,

City
Isfahan

Postal code

Approval date
2015-06-10, 1394/03/20

Ethics committee reference number
ir.mui.rec.1394.3.321

Health conditions studied

1

Description of health condition studied
Herpetic interstitial keratitis

ICD-10 code
H19.1

ICD-10 code description
Herpesviral keratitis and keratoconjunctivitis

Primary outcomes

1

Description
Cornea haziness

Timepoint
Before and 1 month after treatment

Method of measurement
Pentacam optical densitometry

Secondary outcomes

1

Description
Visual acuity

Timepoint
Before and 1 month after treatment

Method of measurement
Snellen chart

Intervention groups

1

Description
Group 1: Intervention group, treatment with topical Cyclosporine 2 % (provided by Sinadarou company) 1 gtt every 12 hours

Category
Treatment - Drugs

2

Description
Group 2: Control group, treatment with topical prednisolone acetate 1% (Precord, Sinadarou company), 1 gtt every 6 hours

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Feiz Hospital

Full name of responsible person
Dr Nayebzade

Street address
Modares St.,

City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
Full name of responsible person
Dr Mehdi Nematbakhsh
Street address
Hezarjerib St., Isfahan University of Medical Sciences, Headquarters No.4 building, Vice-chancellery for Research and Technology
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Isfahan 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
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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