

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3445 2031

##### Email address

peyman@med.mui.ac.ir

##### 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Pourazizi

**Position**

Resident

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## Person responsible for scientific inquiries

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**Position**

Assistant professor

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## Person responsible for updating data

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**Position**

Assistant professor

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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*