

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of clinical effect of topical Prednisolon with and without topical Cyclosporin 2% in the treatment of acute non infectious anterior uveitis

Protocol summary

Summary

The purpose of this study is the evaluation of efficacy of topical Cyclosporin 2% in the treatment of acute anterior non-infectious uveitis. The question is whether the addition of topical Cyclosporin 2%, as an immunosuppressive agent, to topical steroid, which is the mainstay of treatment in acute anterior uveitis, can lead to diminution of topical steroid dosage? The study design is double blind randomized placebo-controlled single center trial. The patients older than 18 years diagnosed as having acute anterior non-infectious uveitis, will be included. Sixty trial patients are randomly assigned into equal groups of 30, group A and B, receiving drop A or drop B, one drop four times daily in addition to topical prednisolon. Drop A and B contain either cyclosporin2% or placebo (artificial tear). The participants and researcher are blind to the type of treatment. The primary outcome is the mean time to remission of intraocular inflammation in each group. The secondary outcome is the side effect(s) of topical cyclosporin2%.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112731135N1**
Registration date: **2017-02-12, 1395/11/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-12, 1395/11/24

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-01-21, 1395/11/02

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical effect of topical Prednisolon with and without topical Cyclosporin 2% in the treatment of acute non infectious anterior uveitis

Public title

The effect of topical Cyclosporin in uveitis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: First episode of acute anterior non-infectious uveitis with +3 or +4 cell in anterior chamber; Completion of informed consent; Older than 18 years; No

history of topical drug consumption; No history of previous ocular surgery; Not pregnant or decision for pregnancy. Exclusion criteria: Exclusion request for any reason at any time; Lack of timely patient; Not compliant patient; The incidence of drug sensitivity

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Mashhad University of Medical Sciences

Street address

Research Chancellor of Mashhad University of Medical Sciences, Ghoreyshi building, Daneshgah Ave, Mashhad, Iran

City

Mashhad

Postal code

Approval date

2015-11-11, 1394/08/20

Ethics committee reference number

IR.MUMS.fm.REC.1394.329

Health conditions studied

1

Description of health condition studied

Acute Anterior Uveitis

ICD-10 code

H20.0

ICD-10 code description

Acute and subacute iridocyclitis Anterior uveitis Cyclitis

Iritis acute, recurrent or subacute

Primary outcomes

1

Description

Mean time to remission of intraocular inflammation

Timepoint

Each 72 hours until complete remission of intraocular inflammation

Method of measurement

with Slit Lamp and according to SUN Group criterion

Secondary outcomes

1

Description

Incidence of ocular complications such as burning, Dryness and tearing

Timepoint

Each 72hours

Method of measurement

Ask from patient

2

Description

Intraocular pressure

Timepoint

Each 72hours

Method of measurement

with Goldman tonometer in mmHg

Intervention groups

1

Description

Patients in the intervention group receiving topical Cyclosporin2% four times daily(in addition to the standard treatment of uveitis) until complete remission of inflammation.

Category

Treatment - Drugs

2

Description

Patients in control group receiving artificial tear four times daily(in addition to standard treatment of uveitis) until complete remission of inflammation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam-Al-Anbia Hospital
Full name of responsible person
Dr. Mohammad Arjmand
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Chancellor of Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Ghoreishi Building, Daneshgah Ave, Mashhad
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Chancellor of Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
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Other areas of specialty/work
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empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty