

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the efficacy and extend of ocular surface toxicity between a preservative- free methylprednisolone topical preparation and preserved prednisolone eye drop in the treatment of acute anterior uveitis

Protocol summary

Summary

Objective: To evaluate the anti-inflammatory efficacy and extend of ocular surface toxicity of nonpreserved methylprednisolone 1% compared with preserved prednisolone acetate suspension 1% eyedrops for management of acute anterior uveitis Design: Prospective, randomized, investigator-masked, comparative clinical trial Setting and conduct: Eyes with non-infectious acute anterior uveitis would be assigned to receive either of study medications eye drops randomly (preservative free methylprednisolone 1% in case group and preserved prednisolon acetate 1% in control group). During the follow-up, anterior chamber cell (based on SUN group classification) and flare (using laser flare photometer- Kowa FM-600) would be evaluated for comparison of the anti-inflammatory effect. Ocular surface toxicity would be assessed by objective ratings of corneal irritation (corneal fluorescein staining scores) and tear film stability indices (tear break-up time, Schirmer I test), as well as questioner-based grading of ocular discomfort parameters. All the measurement would be repeated on each follow-up visit (first and second weeks post treatment) Participants: 60 eligible eyes (60 consecutive patients) with unilateral non-infectious acute anterior uveitis with at least 2+ anterior chamber cells based on SUN group classification Intervention: Receiving either hourly nonpreserved methylprednisolone 1% or preserved prednisolone 1% (Pred Forte 1%, Allergan, Inc) eye drops followed by a 2-week tapering regimen Main outcome: The main outcome measure would be the grade of anterior chamber cell (based on SUN group classification) on day 14.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101511125N1**

Registration date: **2013-03-09, 1391/12/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-09, 1391/12/19

Registrant information

Name

Alireza Hedayatfar

Name of organization / entity

Noor Ophthalmic Research Center

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Funded by Vice chancellor of Noor Research Eye Center (NORC)

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the efficacy and extend of ocular surface toxicity between a preservative- free methylprednisolone topical preparation and preserved prednisolone eye drop in the treatment of acute anterior uveitis

Public title
Comparison of two type of steroidal eyedrops in treatment of uveitis

Purpose
Treatment

Inclusion/Exclusion criteria
Eligibility criteria were: 1- age 16 years or older; 2- attack duration less than one week period; 3- no high intraocular pressure at presentation; 4-negative clues for infectious (e.g. corneal scars, iris atrophy) or granulomatous inflammation (e.g. granulomatous keratic precipitate or iris nodule). The following exclusion criteria would be used: 1-eyes with hypopyon or florid fibrin formation; 2-prior unsuccessful topical treatment; 3-known cases of Behcet disease; 4-any slit-lamp evidence of significant blepharitis or meibomian gland dysfunction; 5-recent use of contact lenses.

Age
From **16 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
ثبت نشده است

Secondary trial Id
ثبت نشده است

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of NOOR OPHTHALMIC RESEARCH CENTER

Street address

NOOR EYE HOSPITAL (7TH FLOOR), 96 ESFANDIAR ST, VALI-E-ASR STt,

City

TEHRAN

Postal code

1968653111

Approval date

2013-01-15, 1391/10/26

Ethics committee reference number

841/ρ

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

Primary outcomes

1

Description

anterior chamber inflammation

Timepoint

1 week and 2 week after treatment

Method of measurement

Anterior chamber flare would be assessed using the laser flare photometer .anterior chamber cell would be assessed using slit lamp by standard grading system (1-4, SUN)

Secondary outcomes

1

Description

Corneal toxicity

Timepoint

1 week and 2 week after treatment

Method of measurement

Schirmer I test, tear break-up time, and corneal fluorescein staining scores

2

Description

Subjective discomfort

Timepoint

1 week and 2 week after treatment

Method of measurement

Questionary

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

In case group: self- instillation of nonpreserved methylprednisolone sodium succinate 1 % every hour one eye drop during daytime for the first week and then upon clinical response

Category

Treatment - Drugs

2**Description**

In control group: self- instillation of preserved prednisolone acetate 1% (Pred Forte 1%, Allergan, Inc) every hour one eye drop during daytime for the first week then upon clinical response

Category

Treatment - Drugs

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

NOOR EYE HOSPITAL

Full name of responsible person

ALIREZA HEDAYATFAR

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NOOR EYE HOSPITAL, 96 ESFANDIAR ST, VALI-E-ASR ST

City

Tehran

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

Vice chancellor for research of Noor Ophthalmic research Center (NORC)

Full name of responsible person

Dr. FARHAD REZVAN

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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 of Noor Ophthalmic research Center (NORC)

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**

NOOR EYE HOSPITAL

Full name of responsible person

Alireza Hedayatfar

Position

Ocular inflammation and Uveitis fellowship

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

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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