

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of topical tacrolimus eye drop 0.05% in treatment of non-necrotizing HSV stromal keratitis.

Protocol summary

Summary

Object: Evaluation of topical tacrolimus eye drop 0.05% in treatment of non-necrotizing herpetic stromal keratitis and decrease its sequels. Inclusion criteria: Cases with non-necrotizing herpetic stromal keratitis that are in active phase of disease. Exclusion criteria: Cases with necrotizing stromal keratitis, History of corneal graft, History of intraocular operation, Trauma, Pregnant and breast feeding women. Intervention: consecutive patients who affected with active phases of non-necrotizing herpetic stromal keratitis that referred to emergency room and ophthalmology clinic divide in 2 equal groups (each group 25 case) randomly. In this study, one group of the patients will underwent conventional treatment for HSK (include oral acyclovir and topical steroid) and in another group, topical tacrolimus eye drop 0.05% four times a day will add to conventional treatment. Before any treatment and after 3 days, one week, two weeks, three weeks and four weeks after treatment the patients underwent full ocular examination including: Best corrected visual acuity, intraocular pressure measurement, Complete slit lamp examination for grading corneal opacity, corneal edema and vascularization and corneal sensation measurement will perform. Primary outcome measure: change in corneal opacity and edema after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102429871N2**

Registration date: **2016-11-17, 1395/08/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-17, 1395/08/27

Registrant information

Name

Mita Akbari

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical sciences, Pro- Vice-Chancellor for research

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of topical tacrolimus eye drop 0.05% in treatment of non-necrotizing HSV stromal keratitis.

Public title

The effect of tacrolimus eye drop in treatment of herpetic corneal ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Cases with non-necrotizing herpetic

stromal keratitis that are in active phase of disease.
Exclusion criteria: Cases with necrotizing stromal keratitis or history of corneal graft, History of intraocular operation and trauma, Pregnant and breast feeding women will exclude for this study.

Age

From **10 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Amiralmomenin Hospital

Street address

17 Shahrivar Street

City

rasht

Postal code

Approval date

2016-10-15, 1395/07/24

Ethics committee reference number

IR.GUMS.REC.1395.219

Health conditions studied

1

Description of health condition studied

herpetic non-necrotizing stromal keratitis

ICD-10 code

H19.1

ICD-10 code description

Herpesviral keratitis and keratoconjunctivitis

Primary outcomes

1

Description

change in corneal opacity and edema

Timepoint

3 days, one week, two weeks, three weeks and four weeks after treatment

Method of measurement

clinical exam and scoring

Secondary outcomes

1

Description

change in corneal vascularization

Timepoint

3days,one week,two weeks,three weeks and four weeks after treatment

Method of measurement

clinical exam and scoring

Intervention groups

1

Description

Conventional treatment for Non- necrotizing herpetic stromal keratitis including (oral acyclovir 400 mg 5 times a day for 10 days and topical prednisolone acetate 1% eye drop every 2 hours with tapering regarding to inflammatory response).

Category

Treatment - Drugs

2

Description

In another group,beside conventional treatment with oral acyclovir(400mg, 5 times a day for 10 days) and topical prednisolone acetate 1% eye drop every 2 hours with tapering, topical tacrolimus eye drop 0/05% four times a day for one month will prescribe.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Mitra Akbari

Street address

17 Shahrivar Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences, Pro-Vice -
Chancellor for research

Full name of responsible person

Mrs Susan Komaie

Street address

17 Shahrivar Street

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan University of Medical Sciences, Pro-Vice -
Chancellor for research

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

Guilan University of Medical Sciences

Full name of responsible person

Dr Mitra Akbari

Position

Assistant Professor

Other areas of specialty/work

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Shila Kianmehr

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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