Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 It's 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 devide 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, intra ocular 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

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical sciences, Pro- Vice-Chanceller 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 stormal 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
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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

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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