Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the efficacy of mitomycin c 0.01%versus dexamethason 0.1% in treatment of refractory in Vernal Keratoconjunctivitis keratoconjunctivitis

Protocol summary

Summary

Vernal keratoconjunctivitis is a common health problem. the objective of this randomized, double blind is to comparison of the efficacy of mitomycin c 0.01% and dexamethason 0.1% in refractory keratoconjunctivitis. In this study 30 patients with refractory keratoconjunctivitis who to meet the Inclusion/exclusion criteria and randomly assigned into intervention or control group. The patients in the intervention group will receive mitomycin c 0.01%. The patients in the control group will receive dexamethason 0.1%. Outcome efficacy of drugs on symptom: photophobia, tearing, itching, discharge and sing: conjunctival injection, upper lid conjunctival hypertrophia, doctal keratitis, trantas dot, limbal edema compare together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110097743N1**
Registration date: **2012-02-29, 1390/12/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-02-29, 1390/12/10

Registrant information

Name

Nooshin Bazzazi

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of mitomycin c 0.01%versus dexamethason 0.1% in treatment of refractory in Vernal Keratoconjunctivitis keratoconjunctivitis

Public title

Comparison of mitomycin and dexametoson in Vernal Keratoconjunctivitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria :the paitient with Refractory Vernal Keratoconjunctivitis. Exclusion criteria :croneal and conjunctivitis complication due to mitomycin c 0.01% efficacy of drugs.

Age

From **6 years** old to **75 years** old

Gender

Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamedan University of Medical Sciences
Street address
Bolvar eram-Hamedan
City
Hamedan
Postal code
-
Approval date
2011-08-03, 1390/05/12
Ethics committee reference number
16/35/9/786/پ/د

Health conditions studied

1

Description of health condition studied
vernal keratoconjunctivitis
ICD-10 code
H 10.1
ICD-10 code description
vernal conjunctivitis

Primary outcomes

1

Description
Symptom: photophobia, tearing, itching, discharg to four grad: non complication, mild, modrat (complication half of day), sever (complication whole day)
Timepoint
Befor and after treatment (after 20 days)
Method of measurement
Qestion

2

Description
Conjunectival injection whit 4 grade;no injection-mild-modrat-sever bolbar injection
Timepoint
Befor and after treatment (after 20 days)
Method of measurement
Examination

3

Description
Upper lid conjunectival hyperthrophy with 4grade:no-mild -modrat and sever pupillary hyperthrophia
Timepoint
Befor and after treatment (after 20 days)
Method of measurement
Examination

4

Description
Puncted keratitis with 4 grade :no-Puncted in 1/4 serface of cornoal-Puncted in 1/2 serface of cornoal-Puncted in >3/4 serface of cornoal
Timepoint
Befor and after treathmen(after 20 days)t
Method of measurement
Examination

Secondary outcomes

1

Description
Trantarsal dot with 4 grade:no-(1-2)dot-(3-4)dot->4dot
Timepoint
Befor and after treathment(after 20 days)
Method of measurement
Examination

2

Description
Limbal edema with 4 grade:no-<90 degree limbal area-(90-180)degree limbal area->180 degree limbal area
Timepoint
Befor and after treathment(after 20 days)
Method of measurement
Examination

Intervention groups

1

Description
Intervention group :drop mytomicen 0/01% in duration 20 days,dievided 4,2qtt

Category
Treatment - Drugs

2

Description
Control group:The patients will receive drop Dexamethazon phosphat 0/1% in duration 20 days,divided 4,2qtt
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamedan Univercity of Medical Sciences
Full name of responsible person
Bazzazi-Azimi
Street address
Hamedan Farshchian Hospital
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Bazzazi/Azimi
Street address
Hamedan
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan Univercity of Medical Sciences
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Nooshin Bazzazi
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Person responsible for updating data

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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