Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Comparison of effect of topical ophthalmic drop tacrolimus 1% versus topical ophthalmic drop dexamethasone 1% in the treatment of patients with shield ulcer

Protocol summary

Summary

(1)objective: comparison of effect of topical ophthalmic drop tacrolimus 1% versus topical ophthalmic drop dexamethasone 1% in the treatment of patients with shield ulcer; (2)study design: Randomized, convenience sampling and dividing the patients into two groups based on the permutation blocks,double-blind for both groups of the study, controlled with medication, single-center, phase II trial; (3)study population: patients with diagnosis of shield ulcers; (4) main inclusion criteria: no history of any eye disease, eye trauma, eye surgery and lens usage, no use of concomitant other drugs, no usage of corticosteroids ten days before entering the study; (5)main exclusion criteria: simultaneous eye disease, eye trauma, surgery, smoking and steroid usage lens ten days before entering the study; (6)sample size:10 patients in each group and a total of 20; (6)interventions: administration of topical ophthalmic drop tacrolimus 1% in the first group and topical ophthalmic drop dexamethasone 1% in the second group for 3 months; (7)intervention time: at the time of diagnosis for 3 months; (8)primary outcomes: reduced size of shield ulcer, corrected visual acuity, reepithialization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110630746N1**
Registration date: **2016-12-25, 1395/10/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-25, 1395/10/05

Registrant information

Name

Nima Rastgar Rad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 0178

Email address

rrnima88@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

Expected recruitment start date

2015-07-29, 1394/05/07

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of topical ophthalmic drop tacrolimus 1% versus topical ophthalmic drop dexamethasone 1% in the treatment of patients with shield ulcer

Public title

Comparison of effect of topical ophthalmic drop tacrolimus 1% versus topical ophthalmic drop dexamethasone 1% in the treatment of patients with shield ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: no history of any eye disease; eye trauma, eye surgery and lens usage; no use of concomitant other drugs; no usage of corticosteroids ten days before entering the study Exclusion criteria: simultaneous eye disease; eye trauma, surgery; smoking and steroid usage lens ten days before entering the study

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Ethics Committee of Zahedan University of Medical Sciences

Street address

Ethics Committee of Zahedan University of Medical Sciences, Zahedan University of Medical Sciences, Dr.Hesabi Square, Zahedan

City

Zahedan

Postal code

Approval date

2015-06-28, 1394/04/07

Ethics committee reference number

IR.zaums.rec.1394.63

Health conditions studied

1

Description of health condition studied

Keratities

ICD-10 code

H16.0

ICD-10 code description

Corneal ulcer

Primary outcomes

1

Description

Reepithialization

Timepoint

2 weeks, 1 month, 2 months, 3 months after intervention and 1 months after intervention deadline

Method of measurement

Physical examination by Ophthalmologist

2

Description

Shield ulcer's size

Timepoint

2 weeks, 1 month, 2 months, 3 months after intervention and 1 months after intervention deadline

Method of measurement

Based on physical examination by slit lamp

3

Description

Corrected visual acuity

Timepoint

2 weeks, 1 month, 2 months, 3 months after intervention and 1 months after intervention deadline

Method of measurement

Based on physical examination by snellen chart

Secondary outcomes

empty

Intervention groups

1

Description

Group 1: administration of topical ophthalmic drop tacrolimus 1% of Zahravi-Tehran company one drop every 12 houre for 3 months

Category

Treatment - Drugs

2

Description

Group 2: administration of topical ophthalmic drop dexamethasone 1% of Tehran-Daroupakhsh company one drop every 12 houre for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Eye Hospital
Full name of responsible person
Nima Rastgar Rad
Street address
Al-Zahra Eye Hospital, Shahid Motahari(Airport) Blvd., Zahedan, Sistan and Baluchestan, Iran.
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Zahedan University of Medical Sciences
Full name of responsible person
Mohsen Taheri
Street address
Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan
City
Zahedan
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, Zahedan 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
Zahedan University of Medical Sciences
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Nima Rastgar Rad
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Ophthalmology Residence
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Web page address

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