

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

Keratitis

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 hours 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 hours 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

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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

Full name of responsible person

Nima Rastgar Rad

Position

Ophthalmology Residence

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

Al-Zahra Eye Hospital, Shahid Motahari(Airport) Blvd.,

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Position

Associate Professor of Ophthalmology

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Position

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Email**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