

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of topical cyclosporine 0.05% impact on pterygium recurrence in patients undergoing pterygium surgery in Amirmomenin Hospital, Rasht

Protocol summary

Study aim

To determine the impact of topical cyclosporine 0.05% on inflammation, recurrence and complications of pterygium surgery

Design

Patients with a Pterygium larger than 3 mm at horizontal width over the cornea on Slit-lamp exam who are candidates for surgery. Patients who were included were assigned randomly into 2 groups. One group receiving topical drops of corticosteroids, antibiotic and cyclosporine and the other group receiving only topical drops of corticosteroids and antibiotic. On post operative day 1, 3, 7, 30, 90 and 6 months after surgery patients corrected visual acuity, clinical inflammation grading, time for epithelial defect to repair and complications of surgery and recurrence of pterygium will be examined and compared in these 2 groups.

Settings and conduct

The study will be conducted in the eye clinic of Amirmomenin hospital. The study will be single-blind and patients will not be informed of the addition of cyclosporine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with a Pterygium larger than 3 mm at horizontal width over the cornea on Slit-lamp exam who are candidates for surgery. Non inclusion criteria: patients with previous pterygium recurrence; pseudo-ptyerygium; pregnant and breastfeeding mothers; systemic disease like diabetes and heart disease; ocular surface disease like keratitis or dry eye or conjunctivitis; prior ocular surgery within 6 months; hypersensitivity to cyclosporine.

Intervention groups

Patients who were included were assigned randomly through block randomization using blocks of size 4. Group A: Patients receiving topical drops of corticosteroids, antibiotic and cyclosporine. Group B:

Patients receiving topical drops of corticosteroids and antibiotic.

Main outcome variables

Clinical inflammation grading and pterygium recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160919029871N4**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Mita Akbari

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of topical cyclosporine 0.05% impact on pterygium recurrence in patients undergoing pterygium surgery in Amiralmomenin Hospital, Rasht

Public title

Topical cyclosporine 0.05% impact on pterygium recurrence in patients undergoing pterygium surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with a Pterygium larger than 3 mm at horizontal width over the cornea on Slit-lamp exam who are candidates for surgery

Exclusion criteria:

Patients with previous pterygium recurrence, pseudo-terygium Pregnant and breastfeeding mothers, systemic disease like diabetes and heart disease Ocular surface disease like keratitis or dry eye or conjunctivitis Prior ocular surgery within 6 months Hypersensitivity to cyclosporine

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who were included were assigned randomly through block randomization using blocks of size 4. Group A: Patients receiving topical drops of Corticosteroids, Antibiotic and cyclosporine. Group B: Patients receiving topical drops of Corticosteroids and Antibiotic.

Blinding (investigator's opinion)

Single blinded

Blinding description

The addition of Cyclosporine drop was not explained to the patients

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Siadaty St., Namju St., Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2019-08-03, 1398/05/12

Ethics committee reference number

IR.GUMS.REC.1398.248

Health conditions studied**1****Description of health condition studied**

Pterygium

ICD-10 code

H11.0

ICD-10 code description

Pterygium of eye

Primary outcomes**1****Description**

Clinical inflammation grading and pterygium recurrence

Timepoint

Day 1, 3, 7, 30, 90 and 6 months after surgery

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Aside from the routine topical Bethamethasone and Antibiotic drops the intervention group will receive topical drops of cyclosporine (0.05%) for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Patients receiving topical drops of Corticosteroids and Antibiotic

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital, Rasht

Full name of responsible person

Dr Mitra Akbari

Street address

Eye Research Center, Amiralmomenin Hospital, 17 Shahrivar St, Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Mitra Akbari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data

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Position

Researcher

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available