

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of effect of Cyclosporine ophthalmic emulsion 2% and Betamethasone eye drop on intraocular pressure, conjunctival hyperemia and subjective dry eye symptoms following trabeculectomy in primary open angle glaucoma (POAG) patients.

Protocol summary

Summary

Objectives: to compare effects of cyclosporine 2% and betamethasone eye drops on surgical results of trabeculectomy in primary open angle glaucoma patients. Design: triple blind, prospective randomized clinical trial Setting and Conduct: the study takes place in Eye Research Center, Mashhad University of Medical Sciences. In appropriate subjects according to the study criteria, a standard trabeculectomy will be done. In first postoperative day and according to a random digit table, the patients will be allocated in group A or B. A pharmaceutical company, would provide the cyclosporine 2% and betamethasone eye drops in similar bottles with blinded labels (A or B) and disclose the content of each bottle only at the conclusion of study. The patients and researchers are masked to the study groups. Participants: Patients with primary open angle glaucoma with uncontrolled intraocular pressure or progressive disease, despite maximally tolerable medical therapy, would be included in the study. The following exclusion criteria will be respected: age<20 years; previous surgery in same eye; candidate for combined surgery; pregnancy; breast feeding; monocular subjects; allergy to eye drops. Intervention: following surgery and allocation to the study groups, monthly observation of clinical status will be done. In each visit a complete set of ophthalmic examinations along with slit-lamp photography of bleb area will be done. Main outcome measures: intraocular pressure; dry eye symptoms; bleb morphology (IBAGS)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706111154N1**

Registration date: **2013-09-23, 1392/07/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-23, 1392/07/01

Registrant information

Name

Ramin Danehvar

Name of organization / entity

Eye Research Center, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1728 1401

Email address

daneshvarr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2013-09-11, 1392/06/20

Expected recruitment end date

2015-01-10, 1393/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of Cyclosporine ophthalmic emulsion 2% and Betamethasone eye drop on intraocular pressure, conjunctival hyperemia and subjective dry eye symptoms following trabeculectomy in primary open angle glaucoma (POAG) patients.

Public title

A study to evaluate the effect of cyclosporine 2% eye drop on surgical result of glaucoma surgery (trabeculectomy)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: POAG patient with insufficient IOP control on maximal tolerable medical therapy (MTMT), undergoing primary trabeculectomy with MMC augmentation. Exclusion Criteria: Age <20 years; History of previous ocular surgery in the same eye; Candidate for combined surgery; Pregnancy; Breast feeding; Monocular subject; Allergy to any topical antiglaucoma medication, or cyclosporine

Age

From **20 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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, Mashhad University of Medical Sciences

Street address

Ghoreishi building, Daneshgah street

City

Mashhad

Postal code

91375345

Approval date

2013-08-17, 1392/05/26

Ethics committee reference number

911251

Health conditions studied

1

Description of health condition studied

glaucoma

ICD-10 code

H40.1

ICD-10 code description

Primary Open-Angle Glaucoma

Primary outcomes

1

Description

intraocular pressure (IOP)

Timepoint

monthly

Method of measurement

Goldmann applanation tonometer (GAT)

2

Description

bleb morphology

Timepoint

monthly

Method of measurement

clinical observation and slit photography (IBAGS)

3

Description

Subjective dry eye symptoms

Timepoint

monthly

Method of measurement

questionnaire

Secondary outcomes

1

Description

success rate

Timepoint

Mid-term success rate (6 month following surgery) would be evaluated.

Method of measurement

clinical exam

2

Description

complication rate

Timepoint

Midterm complication rate (6 month following surgery) would be evaluated.

Method of measurement

clinical exam

3

Description

visual acuity

Timepoint

monthly

Method of measurement

clinical exam (logMAR)

Intervention groups

1

Description

Case Group: In the first postoperative day following a standard, fornix-based trabeculectomy, ophthalmic emulsion of cyclosporine A, 2%, every 4 hours for the first postoperative week and every 6 hours for the next 3 weeks will be prescribed for the patients.

Category

Treatment - Drugs

2

Description

Control Group: In the first postoperative day following a standard, fornix-based trabeculectomy, betamethasone eye drop, every 4 hours for the first postoperative week and every 6 hours for the next 3 weeks will be prescribed for the patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Eye Research Center, Mashhad University of Medical Sciences

Full name of responsible person

Ramin Daneshvar, MD

Street address

Khatam Eye Hospital, Gharani Blvd.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Ramezani

Street address

Ghoreishi Building, Daneshgah Street

City

Mashhad,

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, Mashhad 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

Eye Research Center, Mashhad University of Medical Sciences

Full name of responsible person

Parisa Rajaei; Marzieh Saadat

Position

Research Secreterist

Other areas of specialty/work

Street address

Khatam Anbia Eye Hospital, Gharani Blvd

City

Mashhad

Postal code

91959-61151

Phone

+98 51 1728 9911

Fax

Email

erc@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Eye Research Center, Mashhad University of Medical Sciences

Full name of responsible person

Ramin Daneshvar, MD

Position

Assistant Professor of Ophthalmology; Fellowship in Glaucoma; MD

Other areas of specialty/work

Street address

Khatam Anbia Eye Hospital, Gharani Blvd.,

City

Mashhad

Postal code

91959-61151

Phone

+98 51 1728 9911

Fax**Email**

radaneshvar@gmail.com; daneshvarr@mums.ac.ir

Web page address**City**

Mashhad

Postal code

91959-61151

Phone

+98 51 1728 9911

Fax

+98 51 1728 9911

Email

radaneshvar@gmail.com; daneshvarr@mums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Eye Research Center, Mashhad University of Medical
Sciences

Full name of responsible person

Ramin Daneshvar, MD

Position

Assistant Professor of Ophthalmology, Glaucoma
Fellowship, MD

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

Khatam Anbia Eye Hospital, Gharani Blvd.,

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