

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

the effect of cyclosporine % 0/05 compared with tearlose on post cataract surgery dry eye

Protocol summary

Study aim

Determination of the effect of 0.05% cyclosporine on dry eye after cataract surgery

Design

This clinical trial study was performed on 50 patients who were candidates for cataract surgery referred to Bu Ali Sina Hospital in Sari with a control group with parallel, single-blind, randomized phase 2 on 50 patients for randomization of random allocation software.

Settings and conduct

The study site of Bu Ali Hospital in Sari was studied on 50 patients who were divided into two groups of 25. Group T and group C, intervention group or C in addition to a fixed treatment regimen of 0.05% cyclosporine drops, 4 times a day for 4 weeks and in the control group or Artificial tear drops were used 4 times a day for 4 weeks. Patients were followed up at intervals of day 1, day 7 and day 30 after surgery, and on day 30 after surgery, the necessary dry eye examinations were performed for patients at Bu Ali Sina Hospital. Participating in the study and clinical caregiver The evaluator in this study will be blind. Only the methodological consultant had access to the list.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for cataract surgery over 40 years Exclusion criteria: Significant preoperative dry eye ($T_{but} \leq 10$, $ST-I \leq 10$), Presence of systemic diseases, Use of drugs with the effect of dry eye, Existence of complications during or after cataract surgery, Pregnant and lactating mothers

Intervention groups

Intervention group: Includes group therapy patients who used 0.05% cyclosporine drops in addition to the fixed post-cataract treatment regimen (betamethasone / chloramphenicol). Control group: includes group therapy patients who, in addition to a fixed treatment regimen after cataract surgery (betamethasone / chloramphenicol), also used tyrollose drops or artificial tears.

Main outcome variables

Dry eyes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211227053548N1**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

Registration date

2022-01-19, 1400/10/29

Registrant information

Name

Hanieh Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3320 3358

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of cyclosporine % 0/05 compared with tearlose on post cataract surgery dry eye

Public title

The effect of cyclosporine eye drops compared to artificial tears for dry eye after cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate patients for cataract surgery Age over 40 years

Exclusion criteria:

Sever dry eye(Tbut ≤ 10 , ST-I ≤ 10) Existence of systemic diseases such as uncontrolled diabetes ,Lupus, rheumatoid arthritis and ... Use of drugs with the effect of dry eye, such as anti-glaucoma drugs Complication in or post cataract surgery:endophthalmitis,nucleous drop,keratopathy,macular edema and retinal detachment Pregnant and breast feeding mother

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization method is used to randomized the patients. For randomization, we visited the www.sealedenvelope.com, then randomization tab and make a list option were selected, the number of intervention groups, sample size, block size (4) were entered the intended locations, then a random list containing the pattern of patient allocation was obtained in two groups

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo is prepared by the Department of Pharmacy, School of Pharmacy, Mazandaran University of Medical Sciences, Iran in a completely similar way to the drug (cyclosporine). The droppers (containing medicine or placebo) will be provided to eligible patients by the ward pharmacy based on a random allocation list. Patients, physicians, pharmacists, and ward nurses are unaware of the groups. Unique codes are used instead of letters to blind groups.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Mazandaran university ethics committee

Street address

Joybar three way,mazandaran univercity of medical sciences

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2021-09-01, 1400/06/10

Ethics committee reference number

IR.MAZUMS.REC.1400.435

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

Post cataract surgery dry eye

ICD-10 code

H26

ICD-10 code description

Other cataract

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

Dry eye

Timepoint

1month post cataract surgery

Method of measurement

Osid,tbut test,schirmer1 test

Secondary outcomes**1****Description**

Eye irritation

Timepoint

One day,one week and 1month post surgery

Method of measurement

Osid

2

Description

eye's pain

Timepoint

One day,one week and 1month post surgery

Method of measurement

Osid

3

Description

eye redness

Timepoint

One day,one week and 1month post surgery

Method of measurement

Osid

Intervention groups

1

Description

Intervention group: Cyclosporine drops of% 0.05, which is given to the patient every 6 hours every 6 hours after surgery for a fixed treatment regimen, including steroid eye drops, and the drops are the product of Sina Daru Company. Patients are fully followed up at intervals of day 1, day 7 and day 30 after surgery, and on day 30 after surgery, the necessary dry eye examinations are performed for patients at Bu Ali Sina Hospital.

Category

Treatment - Drugs

2

Description

Control group: Adding drops of Tyrol or artificial tears, which are given to the patient every 6 hours every 6 hours after surgery for a fixed period of 4 weeks, including steroid eye drops, and the drops are the product of Sina Daroo Company. Patients are fully followed up at intervals of day 1, day 7 and day 30 after surgery, and on day 30 after surgery, the necessary dry eye examinations are performed for patients at Bu Ali Sina Hospital. It is administered every 6 hours after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Boalisina hospital

Full name of responsible person

Hanieh ahmadi

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Pasdaran blv

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name

Ww

Grant code / Reference number

344

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Ghh

Proportion provided by this source

4

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

Mazandaran University of Medical Sciences

Full name of responsible person

Hanieh ahmadi

Position

Assistan professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hanieh ahmadi

Position

Assistan professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is confidential

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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