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 (Tbut ≤10, ST-I≤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 tyrolose 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
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Iran (Islamic Republic of)
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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
1mounth post cataract surgery

Method of measurement
Osid,tbut test,schirmer1 test

Secondary outcomes

1

Description
Eye irritation

Timepoint
One day,one week and 1mounth post surgery

Method of measurement

Osid

2

Description
eye's pain
Timepoint
One day,one week and 1mounth post surgery
Method of measurement
Osid

3

Description
eye redness
Timepoint
One day,one week and 1mounth 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
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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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Latest degree

Subspecialist

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Latest degree

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Email

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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