

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of prophylactic effect of Betaxolol 0.5% with Brimonidine 0.2% on IOP elevation after Nd: YAG Laser posterior capsulotomy in patients with posterior capsule opacity

Protocol summary

Study aim

To compare the prophylactic effect of Betaxolol 0.5% with Brimonidine 0.2% on IOP elevation after Nd: YAG Laser posterior capsulotomy

Design

A clinical trial study with parallel, double-blinded, randomized groups

Settings and conduct

In the specialized and sub-specialized polyclinic of Kowsar hospital (Semnan University of Medical Sciences), eligible patients are randomly allocated into two groups. One hour before the laser application, In group 1 one drop of betaxolol 0.5 % and in group 2, one drop of brimonidine 0.2 % is instilled into the lower fornix of the eye by the nurse. The patient closes his or her eyes for one minute. 10 minutes later one drop of tropicamide 1% is instilled. Patients' intraocular pressure is measured and recorded by the ophthalmologist one hour before Nd:YAG laser posterior capsulotomy and four hours after it. Data analysis is performed by an assistant professor of epidemiology and biostatistics.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with posterior capsule opacity following uncomplicated cataract surgery 2. Age over 21 years; Exclusion criteria: 1. Patients with glaucoma (or history of glaucoma surgery), cup to disc ratio greater than 0.5, intraocular pressure greater than 21 mmHg, active uveitis, active ocular infection 2. Taking systemic or topical alpha 2 agonists, prostaglandin analogues, beta-blockers, carbonic anhydrase inhibitors, parasympathomimetics 3. Pregnancy, unstable cardiovascular condition, severe asthma and lung diseases

Intervention groups

In group 1, a drop of betaxolol 0.5 % (Sina Darou) and in group 2, a drop of brimonidine 0.2 % (Sina Darou) is instilled into the lower fornix, one hour before the laser

application.

Main outcome variables

Intraocular pressure

General information

Reason for update

The study has been finished. because of COVID-19 pandemic, study's sample size is less than the estimated sample size. Some parts of the methodology and language grammar need to be corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200901048577N1**

Registration date: **2020-09-23, 1399/07/02**

Registration timing: **retrospective**

Last update: **2021-05-14, 1400/02/24**

Update count: **1**

Registration date

2020-09-23, 1399/07/02

Registrant information

Name

Elnaz Saber

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3386 2847

Email address

lnaz_saber@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

2019-08-23, 1398/06/01

Actual recruitment end date

2020-05-21, 1399/03/01

Trial completion date

2020-05-21, 1399/03/01

Scientific title

Comparison of prophylactic effect of Betaxolol 0.5% with Brimonidine 0.2% on IOP elevation after Nd: YAG Laser posterior capsulotomy in patients with posterior capsule opacity

Public title

Betaxolol 0.5% versus Brimonidine 0.2% prophylactic effect on IOP elevation after Nd: YAG Laser posterior capsulotomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with PCO after cataract surgery above 21 years old

Exclusion criteria:

Patients with glaucoma (or history of glaucoma surgery) cup to disc ratio greater than 0.5 intraocular pressure greater than 21 mmHg active uveitis active ocular infection pregnancy unstable cardiovascular condition severe asthma and lung disease Taking systemic or topical alpha 2 agonists, prostaglandin analogues, parasympathomimetics, beta-blockers, carbonic anhydrase inhibitors

AgeFrom **21 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **40**Actual sample size reached: **38****Randomization (investigator's opinion)**

Randomized

Randomization description

Block Randomization: In this study, the randomized block method is used to allocate the participants into two groups. Each block will have 4 units (2 units related to intervention group and 2 units related to comparison group). There will be 6 different combinations of intervention and comparison in each block. Using the computer-generated random numbers, one of the combinations is selected. In this way, patients are balanced into two groups of intervention and

comparison.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are randomly allocated into two groups. In group 1, a drop of betaxolol 0.5 % and in group 2, a drop of brimonidine 0.2%, one hour before the laser application, is instilled into the lower fornix by the nurse. The patients do not know the type of the drug (betaxolol or brimonidine). Patients' intraocular pressure is measured and recorded by an ophthalmologist, one hour before laser application and four hours after it. The ophthalmologist also does not know the type of the drug that has been used. The data analysis is performed by an assistant professor of epidemiology and biostatistics who does not know which drug has been used. The information collected by the ophthalmologist and the nurse and the data analysis are given to the student who is responsible for drafting the article.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Semnan University of Medical Sciences

Street address

Golestan town, Amin street, Kosar hospital

City

semnan

Province

Semnan

Postal code

3519899951

Approval date

2020-08-05, 1399/05/15

Ethics committee reference number

IR.SEMUMS.REC.1399.142

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

posterior capsule opacification

ICD-10 code

H25

ICD-10 code description

Age-related cataract

Primary outcomes

1

Description

Intraocular pressure

Timepoint

1 hour before laser application and 4 hours after that

Method of measurement

Goldmann Applanation tonometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: one drop of betaxolol 0.5% (Sina Darou) is instilled into the lower fornix of the eye, 1 hour before Nd:YAG laser posterior capsulotomy.

Category

Treatment - Drugs

2

Description

Intervention group 2: one drop of brimonidine 0.2 % (Sina Darou) is instilled into the lower fornix of the eye, 1 hour before Nd:YAG laser posterior capsulotomy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Navid Elmi Sadr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz kokhayi

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P_kokha@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Elnaz Saber

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data can be shared without disclosing the identities of the participants

When the data will become available and for how long

Access period starts one year after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is no more information

From where data/document is obtainable

Contact the person in charge of the scientific inquiries of the project by e-mail.

What processes are involved for a request to access data/document

After receiving the request e-mail, if the person is eligible, the data will be sent.

Comments