

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**Age**

From **21 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

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

**Sample size**

Target 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

##### Street address

Golestan town , Amin street

##### City

Semnan

##### Province

Semnan

##### Postal code

3519899951

##### Phone

+98 23 3344 1022

##### Email

kosarhos@semums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Parviz kokhayi

#### Street address

Golestan town , amin street , kosar hospital

#### City

Semnan

#### Province

Semnan

#### Postal code

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#### Phone

+98 23 3344 1022

#### Email

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

##### Street address

Golestan town , Amin street , Kosar hospital

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##### Province

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##### Postal code

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## Person responsible for scientific inquiries

### Contact

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**Position**

Assistant Professor

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## Person responsible for updating data

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**Position**

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**Phone**

+98 23 3344 1022

**Email**

Lnaz\_saber@yahoo.com

## 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**