Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Aug 2021

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 briminidine 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

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Iran (Islamic Republic of)

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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, parasymapathomimetics, 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
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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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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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Person responsible for updating data

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Position
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Latest degree
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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