Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of labetalol and esmolol intravenous infusion in the prevention of cardiovascular complications and ischemic changes in patients with chronic hypertension during cataract surgery under local anesthesia with sedation

Protocol summary

Study aim
If it is determined that each of the drugs esmolol and labtalol by intravenous injection method are more effective in preventing cardiovascular complications in patients with chronic hypertension during cataract surgery by local anesthesia and sedation, they can be used routinely.

Design
Clinical trial without control group, with parallel group, triple blinde, randomized, phase 3 on 70 patients, random allocation software was used for randomization.

Settings and conduct
A triple blind clinical trial in patients with chronic hypertension who are candidates for cataract surgery. The Patients will be under local anesthesia with sedation, and then 5 minutes before the surgery, the first group will be treated with osmolol and the second group will be treated with labtalol, and during the operation, the vital signs of both groups will be recorded and examined. The above study is conducted in Faiz Medical Center

Participants/Inclusion and exclusion criteria
Patients who will be included in the study: 1- Candidate patients for cataract surgery with local anesthesia and sedation based on ASA III-II criteria 2-Patients over 65 years of age and of both sexes with chronic hypertension treated with calcium channel blockers and angiotensin converting enzyme inhibitors Patients who are not eligible for the study: 1-Patients who have a history of drug allergy 2-Patients who have addictions.

Intervention groups
In the first group, 0.5 mg/kg intravenous osmolol, whose volume will be increased to 20 cc by sterile normal saline, will be intravenously infused within two minutes, then in the second group, 0.2 mg/kg intravenous labetalol, whose volume will be increased to 20 cc by sterile normal saline. 20 cc will be delivered and will be intravenously infused within two minutes.

Main outcome variables
Systolic blood pressure, diastolic blood pressure, heart rate, breathing rate, arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221108056442N1**
Registration date: **2022-11-26, 1401/09/05**
Registration timing: **prospective**

Last update: **2022-11-26, 1401/09/05**
Update count: **0**

Registration date
2022-11-26, 1401/09/05

Registrant information

Name
Amirreza Abbasi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 74 3262 0262

Email address
amirrezaabbasi00@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of labetalol and esmolol intravenous infusion in the prevention of cardiovascular complications and ischemic changes in patients with chronic hypertension during cataract surgery under local anesthesia with sedation

Public title

Esmolol and Labetalol in cataract surgury in patient with chronic hypertension.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate patients for cataract surgery Patients over 65 years old

Exclusion criteria:

History of drug allergy Addiction

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the simple randomization method of block randomization (block randomization) we will use. Blocking is usually in order Balance the number of samples assigned to each group To be used in the study. This feature helps researchers to Items that require intermediate analyzes during the sampling process The number of samples assigned to each of the case groups Study is equal. The size of all the blocks is equal and we are in this We will have a three-group trial of 6 blocks of 15. Randomization tools are also used in sequence generation software Random (software allocation Random) is used that Random sequence generation software in addition to simple randomization capable To generate random sequences by block generation method. For hiding We avoid concealment allocation We use the method used to execute the sequence Random refers to study participants, in a way That before the individual is assigned, the assigned group is not specified. With From opaque envelopes sealed in random sequence (envelopes opaque, sealed, numbered Sequentially) in This method uses each of the random sequences created on a card It is registered and the cards are placed in the letter envelopes in order To be. In order to maintain a random sequence, also on the outer surface of the envelope The numbering is done in the same way. Finally the envelope lid The letters are pasted and placed in a box, respectively. At Time to start registration of participants, based on the order of entry of the company Eligible applicants to open one of the envelopes in order And the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The researcher, patients and project partner who will perform the statistical analysis will not be aware of the study (triole blind). The grouping of patients will be recorded on a sheet and given to one of the project colleagues. Patients will receive the standard treatment, but they will not know the type of medicine received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Block 8 , Hezarjerib Ave , Bahar St

City

Esfahan

Province

Isfehan

Postal code

8169615738

Approval date

2022-11-08, 1401/08/17

Ethics committee reference number

IR.MUI.MED.REC.1401.285

Health conditions studied

1

Description of health condition studied

Cardiovascular complications and ischemic changes in patients with chronic hypertension during cataract surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Heart Rate
Timepoint
Before the start of the operation, 5 minutes after the start of the operation, every 15 minutes until the end of the operation
Method of measurement
Cardiac Monitor device

2

Description
Systolic Blood Pressure
Timepoint
Before the start of the operation, 5 minutes after the start of the operation, every 15 minutes until the end of the operation
Method of measurement
In millimeteres of mercury using a Calibrated Barometer

3

Description
Diastolic Blood pressure
Timepoint
Before the start of the operation, 5 minutes after the start of the operation, every 15 minutes until the end of the operation
Method of measurement
In millimeteres of mercury using a Calibrated Barometer

4

Description
Percentage of oxygen Saturation
Timepoint
Before the start of the operation, 5 minutes after the start of the operation, every 15 minutes until the end of the operation
Method of measurement
Pulse oximeter

Secondary outcomes

1

Description
Hypertension
Timepoint
Before the start of the operation, 5 minutes after the start of the operation, every 15 minutes until the end of the operation
Method of measurement
In millimeteres of mercury using a Calibrated Barometer

2

Description
Hypotension
Timepoint
Before the start of the operation, 5 minutes after the start of the operation, every 15 minutes until the end of the operation
Method of measurement
In millimeteres of mercury using a Calibrated Barometer

3

Description
Tachycardia
Timepoint
Before the start of the operation, 5 minutes after the start of the operation, every 15 minutes until the end of the operation
Method of measurement
Cardiac Monitor device

4

Description
Bradycardia
Timepoint
Before the start of the operation, 5 minutes after the start of the operation, every 15 minutes until the end of the operation
Method of measurement
Cardiac Monitor device

Intervention groups

1

Description
Intervention group:0.5 mg/kg of intravenous osmolol, whose volume will be increased to 20 cc by sterile normal saline, 5 minutes before the injection of sedative and sedative drugs and will be intravenously infused within two minutes.
Category
Prevention

2

Description
Intervention group: 0.2 mg/kg body weight of intravenous labetalol, whose volume will be increased to 20 cc by sterile normal saline, will be intravenously infused within two minutes 5 minutes before the injection of sedative and sedative drugs.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz hospital
Full name of responsible person
Darioush Moradi Farsani

Street address
Ayatollah Motahari Street , Qods Sq
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8149644874
Phone
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Email
E-mail.feiz@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Darioush Moradi Farsani
Street address
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Province
Isfehan
Postal code
8164945811
Phone
+98 31 3662 4796
Email
Dmoradi@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Darioush Moradi Farsani
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Esfahan University of Medical Sciences
Full name of responsible person
Amirreza Abbasi
Position
Medical intern
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Isfehan

Postal code

8169615738

Phone

+98 31 3262 0262

Email

Amirrezaabbasi00@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information related to the effectiveness of esmolol and labtalol in reducing cardiovascular complications in cataract surgery candidates with chronic hypertension.

When the data will become available and for how long

Start the access period up to one year after the results are published

To whom data/document is available

Researchers

Under which criteria data/document could be used

Can be used for secondary studies

From where data/document is obtainable

Correspond with dmoradi@med.mui.ac.ir

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

Will be sent after receving the email

Comments