Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Preoperative hemodynamic Changes after Continuing or discontinuing Regular Angiotensin Converting Enzyme Inhibitors before Cataract Surgery a Comparative Study

Protocol summary

Study aim
Perioperative hemodynamic Changes after Continuing or discontinuing Regular Angiotensin Converting Enzyme Inhibitors before Cataract Surgery a Comparative Study

Design
Double blinded randomized clinical trial

Settings and conduct
200 patients in the Khalili Hospital of Shiraz with choronic use of ACEI (Angiotensin Converting Enzyme Inhibitors) or ARB (Angiotensin Receptor Blocker)Intervention group: Chronic ACEI users who do not stop their medication until the surgery. Control group: Chronic ACEI users who discontinue their medication 24 to 12 hours before the surgery. are divided into two groups.

Participants/Inclusion and exclusion criteria
ASA II Patients who are undergoing Cataract Surgery Ejection fraction higher than 40 % Patients with chronic use of ACEI or ARB.

Intervention groups
Intervention group: Chronic ACEI users who do not stop their medication until the surgery. Control group: Chronic ACEI users who discontinue their medication 24 to 12 hours before the surgery.

Main outcome variables
The patient's initial blood pressure will be recorded after entering the operating room and then every 5 minutes after induction of anesthesia and during the operation. In the recovery room, blood pressure will be checked every 10 minutes for 1 hour. The patient's initial heart rate will be recorded after entering the operating room and then every 5 minutes after induction of anesthesia and during the operation. In the recovery room, heart rate will be checked every 10 minutes for 1 hour.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N78**
Registration date: **2019-04-06, 1398/01/17**
Registration timing: **prospective**

Last update: **2019-04-06, 1398/01/17**
Update count: **0**

Registration date
2019-04-06, 1398/01/17

Registrant information

Name
Farzaneh Masihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3647 4270

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masihif@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-05, 1398/02/15

Expected recruitment end date
2019-07-06, 1398/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preoperative hemodynamic Changes after Continuing or

discontinuing Regular Angiotensin Converting Enzyme Inhibitors before Cataract Surgery a Comparative Study

Public title
Preoperative hemodynamic Changes after Continuing or discontinuing Regular Angiotensin Converting Enzyme Inhibitors before Cataract Surgery a Comparative Study

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
ASA II Patients who are undergoing Cataract Surgery Ejection fraction higher than 40 % Patients with chronic use of ACEI (Angiotensin Converting Enzyme Inhibitors) or ARB(Angiotensin Receptor Blocker) .

Exclusion criteria:
Duration of operation more than 90 min Electrolyte imbalance Liver or Kidney dysfunction

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

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

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients randomly enter the study through the randomization chart which is derived from the www.randomization.com.

Blinding (investigator's opinion)
Double blinded

Blinding description
The code and group name of each patient will be placed in a separate envelope and sealed and is delivered to the person who is responsible for the anesthetic of the operating room. He is the only person who is aware of the study group of each patient and will not be involved in other parts of the implementation and data collection.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City
Shiraz

Province
Fars

Postal code
7134844119

Approval date
2018-08-24, 1397/06/02

Ethics committee reference number
IR.SUMS.MED.REC.1397.404

Health conditions studied

1

Description of health condition studied
Cataract

ICD-10 code
H25

ICD-10 code description
Age-related cataract

Primary outcomes

1

Description
Blood pressure

Timepoint
The patient's initial blood pressure will be recorded after entering the operating room and then every 5 minutes after induction of anesthesia and during the operation. In the recovery room, blood pressure will be checked every 10 minutes for 1 hour.

Method of measurement
Pressure cuff

2

Description
Heart Rate

Timepoint
The patient's initial heart rate will be recorded after entering the operating room and then every 5 minutes after induction of anesthesia and during the operation. In the recovery room, heart rate will be checked every 10 minutes for 1 hour.

Method of measurement
Monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Chronic ACEI users who do not stop their medication until the surgery.
Category
Diagnosis

2

Description
Control group: Chronic ACEI users who discontinue their medication 24 to 12 hours before the surgery.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
khalili Hospital
Full name of responsible person
Saeed Khademi
Street address
khalili Hospital, Namazi Square
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7134842119
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
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Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
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sacrc@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Ghadimi
Position
متخصص بیهوشی
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

Contact

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Farzaneh Masihi

Position
BS in anesthesia/English Consultant

Latest degree
Master

Other areas of specialty/work
Others

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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 against our policies.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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