

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 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 chronic 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)

Phone

+98 71 3647 4270

Email address

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

City

Shiraz

Province

Fars

Postal code

7134842119

Phone

+98 71 3647 4270

Email

namazi@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

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

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 36474270

Email

maryam_ghadimi2005@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Saeed Khademi

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 36474270

Email

khademish@sums.ac.ir

5th floor, Mohammad Rasoul Allah Research Tower,
Khalili Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

masihifarzaneh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Others

Street address

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