

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 2026

### A comparative study of two different levels of end exhaustion carbon dioxide pressure with cognitive status of patients after cataract surgery in patients referred to Faiz Hospital in 2017-18

#### Protocol summary

##### Study aim

Comparison of two different level of end Exhaustion of carbon dioxide pressure on cognitive status in patients under cataract surgery

##### Design

This study is a double-blind randomized clinical trial study with parallel groups. 240 patients undergoing cataract surgery will be divided into two groups of 120 with using Random Allocation Software. The effect of two levels of End-tidal carbon dioxide on postoperative cognitive impairment is investigated.

##### Settings and conduct

This study was carried out in Feyz hospital in Isfahan during 219-20. 240 patients undergoing cataract surgery were divided into two groups of 120 each, in the first group the End-tidal carbon dioxide pressure was maintained at 35-40 mmHg and in the second group 40-45 mmHg and the incidence of postoperative cognitive impairment will be determined in to groups. The study was double-blind and the patient and collector were unaware of the patients' allocation to the groups.

##### Participants/Inclusion and exclusion criteria

In this study, 240 patients undergoing cataract surgery general anesthesia with ASA 1,2, above 65 years old , who agreed to participate in the study were enrolled. Patients with a history of allergy to anesthetics drugs or a history of moderate to severe psychiatric disorder are not entered in to the study

##### Intervention groups

Group Intervention 1: End-tidal carbon dioxide level between 35-40 mmHg Group Intervention 2: End-tidal carbon dioxide level between 40-45 mmHg

##### Main outcome variables

Cognitive Disorder

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130311012782N36**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **prospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

##### Registration date

2019-09-15, 1398/06/24

##### Registrant information

##### Name

Ali Mehrabi kushki

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3629 1510

##### Email address

mehrabi@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-22, 1398/06/31

##### Expected recruitment end date

2020-03-18, 1398/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

|                                               |                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| empty                                         |                                                                                                                                                                                                                                                                                                           |
| <b>Scientific title</b>                       | A comparative study of two different levels of end exhaustion carbon dioxide pressure with cognitive status of patients after cataract surgery in patients referred to Faiz Hospital in 2017-18                                                                                                           |
| <b>Public title</b>                           | The effect of two levels of end exhaustion carbon dioxide pressure on the cognitive status of patients undergoing cataract surgery                                                                                                                                                                        |
| <b>Purpose</b>                                | Prevention                                                                                                                                                                                                                                                                                                |
| <b>Inclusion/Exclusion criteria</b>           |                                                                                                                                                                                                                                                                                                           |
| <b>Inclusion criteria:</b>                    | Consent to participate in the study Candidate for cataract surgery under general anesthesia age above 65 years American Society Anesthesiologist:1,2                                                                                                                                                      |
| <b>Exclusion criteria:</b>                    | History of allergy to anesthetic drugs History of moderate or severe psychological disorders                                                                                                                                                                                                              |
| <b>Age</b>                                    | From <b>65 years</b> old                                                                                                                                                                                                                                                                                  |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                      |
| <b>Phase</b>                                  | N/A                                                                                                                                                                                                                                                                                                       |
| <b>Groups that have been masked</b>           | <ul style="list-style-type: none"> <li>Participant</li> <li>Investigator</li> </ul>                                                                                                                                                                                                                       |
| <b>Sample size</b>                            | Target sample size: <b>240</b>                                                                                                                                                                                                                                                                            |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                |
| <b>Randomization description</b>              | 240 patients under cataract surgery were selected and randomly allocated in two groups by Random Allocation Software                                                                                                                                                                                      |
| <b>Blinding (investigator's opinion)</b>      | Double blinded                                                                                                                                                                                                                                                                                            |
| <b>Blinding description</b>                   | Patients are unaware of the level of the end exhaustion carbon dioxide pressure. Also, the level of CO <sub>2</sub> at the end of the expiration of patients will be applied by the researcher and the outcome of the study is determined and recorded by another physician who is unaware of the groups. |
| <b>Placebo</b>                                | Not used                                                                                                                                                                                                                                                                                                  |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                  |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                           |
| <b>Secondary Ids</b>                          | empty                                                                                                                                                                                                                                                                                                     |
| <b>Ethics committees</b>                      |                                                                                                                                                                                                                                                                                                           |

|                                                |                                                                                  |
|------------------------------------------------|----------------------------------------------------------------------------------|
| <u><b>1</b></u>                                |                                                                                  |
| <b>Ethics committee</b>                        |                                                                                  |
| <b>Name of ethics committee</b>                | Ethics committee of Isfahan University of Medical Sciences                       |
| <b>Street address</b>                          | Hezar Jerib Street                                                               |
| <b>City</b>                                    | Isfahan                                                                          |
| <b>Province</b>                                | Isfahan                                                                          |
| <b>Postal code</b>                             | 8174673461                                                                       |
| <b>Approval date</b>                           | 2017-10-17, 1396/07/25                                                           |
| <b>Ethics committee reference number</b>       | ir.mui.rec.1396.3.612                                                            |
| <b>Health conditions studied</b>               |                                                                                  |
| <u><b>1</b></u>                                |                                                                                  |
| <b>Description of health condition studied</b> | Cataract                                                                         |
| <b>ICD-10 code</b>                             | H40.10                                                                           |
| <b>ICD-10 code description</b>                 | Unspecified open-angle glaucoma                                                  |
| <b>Primary outcomes</b>                        |                                                                                  |
| <u><b>1</b></u>                                |                                                                                  |
| <b>Description</b>                             | Cognitive Disorder                                                               |
| <b>Timepoint</b>                               | Until 24 hours after surgery                                                     |
| <b>Method of measurement</b>                   | Mini- Mental Status Examination check list                                       |
| <b>Secondary outcomes</b>                      |                                                                                  |
| <u><b>1</b></u>                                |                                                                                  |
| <b>Description</b>                             | Hemodynamic Disorder                                                             |
| <b>Timepoint</b>                               | Every 15 minutes during operation and recovery                                   |
| <b>Method of measurement</b>                   | Pulse oximetry                                                                   |
| <b>Intervention groups</b>                     |                                                                                  |
| <u><b>1</b></u>                                |                                                                                  |
| <b>Description</b>                             | Intervention group1: Level of End-Tidal Carbon Dioxide is set between 35-40 mmHg |
| <b>Category</b>                                | Treatment - Surgery                                                              |

## 2

### Description

Intervention group2: Level of End-Tidal Carbon Dioxide is set between 40-45 mmHg

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Feyz Hospital

##### Full name of responsible person

Kobra Nasrollahi

##### Street address

Modarres Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3669 2174

##### Email

Nasrollahi@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayesh Haghjoo

##### Street address

Hezar Jarib Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3792 3060

##### Email

haghjoo@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

Najmeh Askarianfard

#### Position

Medical student

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

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Soffeh Street

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#### Province

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#### Postal code

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#### Phone

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#### Email

Na.askarianfard93@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Kourosh Naghibi

#### Position

Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

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#### Province

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#### Phone

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#### Email

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ali Mehrabi

**Position**

statistical consultant

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

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**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174643461

**Phone**

+98 31 3792 8081

**Email**

al.mehrabi@gmail.com

## 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**

Information belongs to government agency

**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**

Yes - There is 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

**Title and more details about the data/document**

Because the information belongs to a government agency, it cannot be shared..

**When the data will become available and for how long**

Any time

**To whom data/document is available**

Any person

**Under which criteria data/document could be used**

Under any circumstances

**From where data/document is obtainable**

Any person, any time

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

Any procedure

**Comments**