Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Name of organization / entity
Isfahan University of Medical Sciences
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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

Scientific title
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

Public title
The effect of two levels of end exhaustion carbon dioxide pressure on the cognitive status of patients undergoing cataract surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in the study Candidate for cataract surgery ander general anesthesia age above 65 years American Society Anesthesiologist:1,2

Exclusion criteria:
History of allergy to anesthesial drugs History of moderate or severe psychological disorders

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
Randomized

Randomization description
240 patients under cataract surgery were selected and randomly allocated in tot two groups by Random Allocation Software

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are unaware of the level of the end exhaustion carbon dioxide pressure. Also, the level of CO2 at the end of the expiration of patients will be apply by the researcher and the outcome of the study is determined and recorded by another physician who is unaware of the groups.

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
Hezar Jerib Street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2017-10-17, 1396/07/25

Ethics committee reference number
ir.mui.rec.1396.3.612

Health conditions studied

1

Description of health condition studied
Cataract

ICD-10 code
H40.10

ICD-10 code description
Unspecified open-angle glaucoma

Primary outcomes

1

Description
Cognitive Disorder

Timepoint
Until 24 hours after surgery

Method of measurement
Mini- Mental Status Examination check list

Secondary outcomes

1

Description
Hemodynamic Disorder

Timepoint
Every 15 minutes during operation and recovery

Method of measurement
Pulse oximetry

Intervention groups

1

Description
Intervention group1: Level of End-Tidal Carbon Dioxide is set between 35-40 mmHg

Category
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
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8174673461
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
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Person responsible for updating data

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Position
statistical consultant

Latest degree
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Epidemiology

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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
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