Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the combination of "dimenhydrinate with metoclopramide" and "dimenhydrinate with ondansetron" with "dimenhydrinate alone" in the prevention of nausea and vomiting after cataract surgery under local anesthesia

Protocol summary

Study aim

Determining and comparing effect of the combination of "dimenhydrinate with metoclopramide" and "dimenhydrinate with ondansetron" with "dimenhydrinate alone" in the prevention of nausea and vomiting after the surgery

Design

A randomized double-blinding clinical trial, with the parallel groups

Settings and conduct

This randomized double-blind clinical trial is carried out at Feyz Hospital in Isfahan. In this study, 160 patients who are candidates for cataract surgery will be admitted and randomly divided into 4 parallel groups. The distilled water, dimenhydrinate-metoclopramide, dimenhydrinate-ondansetron, and dimenhydrinate alone will be prescribed for these four groups half an hour before the induction of anesthesia, respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria include candidates for cataract surgery, the ASA I, II, or III, and stability of hemodynamic status. Exclusion criteria include the history of the motor disease, addicted patients, smoking, allergies to studied drugs, liver, and vestibular disorders, the use of antinausea drugs in the last 24 hours, prolonging the surgery more than 45 minutes.

Intervention groups

Half an hour before induction of general anesthesia (which includes injection of 1 cc of 1% propofol, 1 µg/kg and 0.15 mg/kg of ketamine) in the control group 2 cc of distilled water, in the first intervention group 0.5 mg/kg dimenhydrinate with 0.1 mg/kg metoclopramide, in the second intervention group 0.5 mg/kg dimenhydrinate with 0.4 mg ondansetron and in the third intervention group 0.5 mg/kg dimenhydrinate will be administered alone.

Main outcome variables

Severity of nausea; Severity of vomiting; pain intensity; patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N9**
Registration date: **2020-10-22, 1399/08/01**
Registration timing: **prospective**

Last update: **2020-10-22, 1399/08/01**
Update count: **0**

Registration date

2020-10-22, 1399/08/01

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the combination of "dimenhydrinate with metoclopramide" and "dimenhydrinate with ondansetron" with "dimenhydrinate alone" in the prevention of nausea and vomiting after cataract surgery under local anesthesia

Public title
The effect of the combination of "dimenhydrinate with metoclopramide" and "dimenhydrinate with ondansetron" with "dimenhydrinate alone" in the prevention of nausea and vomiting after the surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for cataract surgery American Society of Anesthesiologists (ASA) physical status classification system equal I, II, and III Stability of patients' hemodynamic status
Exclusion criteria:
History of motor disease Smoking or addicted patients Patients with allergies to the studied drugs Liver and vestibular disorders Taking anti-nausea drugs in the past 24 hours Prolongation of surgery more than 45 minutes.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
160 eligible patients will be simple randomly easily selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into four groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the four study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
To blind the study, the drugs will be prepared by an anesthesiologist before the intervention. In terms of the amount of the drug, all drugs will be reached the same volume using distilled water. These syringes will be coded and placed in the operating room and delivered daily to the anesthesiologist, who will prescribe them without knowing the type of medication. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.
Placebo
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 Jarib Ave, Azadi Square.
City
Isfaha
Province
Isfehan
Postal code
8174673461
Approval date
2020-05-30, 1399/03/10
Ethics committee reference number
IR.MUI.MED.REC.1399.188

Health conditions studied

1

Description of health condition studied
Cataract surgery
ICD-10 code
Z98.4
ICD-10 code description
Cataract extraction status

Primary outcomes

1

Description
Severity of nausea
Timepoint
At the time of discharge from recovery and 2 and 4 hours after leaving recovery
Method of measurement
Visual Analogue Scale

2

Description
Severity of vomiting
Timepoint
At the time of discharge from recovery and 2 and 4 hours after leaving recovery
Method of measurement
Visual Analogue Scale

3

Description
Pain
Timepoint
1 hour after surgery
Method of measurement
Visual Analogue Scale

4

Description
Patient satisfaction
Timepoint
When referring to the ward
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients in this group will be given 2 cc of distilled water half an hour before induction of general anesthesia (which includes injections of 1 cc of 1% propofol, 1 µg / kg, and 0.15 mg/kg of ketamine).
Category
Placebo

2

Description
Intervention group: Patients in this group will be prescribed 0.5 mg/kg dimenhydrinate with 0.1 mg/kg metoclopramide half an hour before induction of general anesthesia (which includes 1 cc of 1% propofol, 1 µg / kg, and 0.15 mg/kg of ketamine)
Category
Treatment - Drugs

3

Description
Intervention group: Patients in this group will be prescribed 0.5 mg / kg dimenhydrinate with 0.4 mg of ondansetron half an hour before induction of general anesthesia (which includes injections of 1 cc of 1% propofol, 1 µg / kg and 0.15 mg / kg of ketamine).
Category
Treatment - Drugs

4

Description
Intervention group: Patients in this group will be given 0.5 mg/kg dimenhydrinate alone half an hour before induction of general anesthesia (which includes injections of 1 cc of 1% propofol, 1 µg/kg, and 0.15 mg/kg of ketamine).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz Hospital
Full name of responsible person
Morteza Heidari
Street address
Ayatollah Modarres Street, Quds Square
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8149644874
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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+98 31 3668 8597
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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

Morteza Heidari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Eye Department, Feyz Hospital.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Morteza Heidari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahshid Masoumi

Position

Non-faculty physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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8189911111

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drmahshid61@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

There is no further information

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