

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 anti-nausea 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

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Isfahan

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

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Ayatollah Modarres Street, Quds Square

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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

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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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

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Person responsible for scientific inquiries

Contact

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Esfahan University of Medical Sciences

Full name of responsible person

Morteza Heidari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Non-faculty physician

Latest degree

Medical doctor

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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

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