

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparative study of the preemptive Dexmedetomidine with Ondansetron effect in reducing the post-operative nausea and vomiting after elective middle ear surgery under general anesthesia

Protocol summary

Study aim

If we find the most effective drug in reducing the post operative nausea and vomiting the patient satisfaction will increase and the expenditure of medical center will decrease.

Design

Clinical trial with control group, with parallel group, three way blind, on 165 patient, random allocating software for randomization

Settings and conduct

The patients referring Alzahra and Ayatollah Kashani hospitals in Esfahan who are candidate for elective middle ear surgery, after obtaining informed consent are divided into three groups, under general anesthesia and intubation, receive drug according to their group, measuring of the severity of the nausea and vomiting in the recovery with visual analog scale (VAS).

Participants/Inclusion and exclusion criteria

Entry condition: the patient between the age 18 to 65 years old who consciously participate in study. Exit condition: liver or heart or kidney failure; death of patient; sensitivity to drugs in study; BMI more than 30.

Intervention groups

After general anesthesia with fentanyl, lidocaine, thiopental and intubation and 15 to 20 minute before making a surgical incision, depending on which of the group O, P, D the patient belongs to receive drug or placebo. group O: 0/1 milligram per kilogram ondansetron; group D: dexmedetomidin 1 microgram per kilogram per minute; group p: 10 cc normal saline in 10 minutes.

Main outcome variables

Mean severity of post operative nausea; frequency of post operative vomiting; the average dose of antiemetic used; the average of first time; antiemetic needed; the first time that the fluid diet tolerated; the average time took to tolerate solid diet; mean patient satisfaction

score; duration of anesthesia of patient; duration of surgery of patient; average length of stay in recovery; average of pain intensity; average time of extubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101211005362N27**

Registration date: **2022-01-22, 1400/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-22, 1400/11/02**

Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

Name

Mohammadreza Safavi

Name of organization / entity

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences, Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 31 1273 2659

Email address

safavi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the preemptive Dexmedetomidine with Ondansetron effect in reducing the post-operative nausea and vomiting after elective middle ear surgery under general anesthesia

Public title

The effect of ondansetron and dexmedetomidine in reducing nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

People who willingly want to participate in the study ASA class 1,2 People between the ages of 18 and 65 y/o No motion sickness or Parkinson's disease

Exclusion criteria:

Heart, liver, kidney failure Previous sensitivity to the drugs used in the study Obese patients (BMI more than 30) Patients with mental retardation Patients who have taken antiemetic before operation. Any change in anesthesia Patient death during surgery Surgeries that cause severe nausea and vomiting, such as surgery on the labyrinth (otosclerosis, cholesteatoma with fistula, etc.)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

165 people are selected by easy random method. The way to randomize is that anesthesiologist from a dark-colored bag containing 165 cards with titles O (Ondansetron), D (Dexmedetomidine), P (placebo) that there are 55 of each card, and according to the card that is picked up the patient enters the investigation. (Output card will not be replaced).

Blinding (investigator's opinion)

Triple blinded

Blinding description

Drug injections are performed by an anesthesiologist without knowing the contents of the syringes. (Also, all syringes have the same color and volume). The way to randomize is that anesthesiologist from a dark-colored

bag containing 165 cards with titles O (ondansetron), D (dexmedetomidine), P (placebo) that there are 55 of each card, and according to the card that is picked up The patient enters the investigation.(Output card will not be replaced). Patients also do not know about the medication they are receiving.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Esfahan university of medical sciences

Street address

Heza Jjarib street, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.MUI.MED.REC.1400.501

Health conditions studied**1****Description of health condition studied**

Post operative nausea and vomiting

ICD-10 code

R11.0

ICD-10 code description

Nausea after surgery; Postoperative nausea; Nausea NOS; Nausea without vomiting

Primary outcomes**1****Description**

Mean severity of post operative nausea

Timepoint

Every 15 minutes for 1 hour and then every 6 hours for 24 hours

Method of measurement

Visual analog scale

2

Description

Frequency of post operative vomiting

Timepoint

Every 15 minutes for 1 hour and then every 6 hours for 24 hours

Method of measurement

According to percentage

3

Description

The average dose of antiemetic used

Timepoint

In the recovery and the first 24 hours after surgery

Method of measurement

Dose of drug used

4

Description

The average of first time, antiemetic needed

Timepoint

In the recovery and the first 24 hours after surgery

Method of measurement

Time that drug used

5

Description

The first time that the fluid diet tolerated

Timepoint

The first 24 hours after surgery

Method of measurement

Time the diet tolerated

6

Description

The average time took to tolerate solid diet

Timepoint

The first 48 hours after surgery

Method of measurement

Time the diet tolerated

7

Description

Mean patient satisfaction score

Timepoint

The first 24 hours after surgery

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Duration of anesthesia of patient

Timepoint

During the operation and 24 hour after that

Method of measurement

Minute

2

Description

Duration of surgery of patient

Timepoint

During the operation

Method of measurement

Minute

3

Description

Average length of stay in recovery

Timepoint

During the presence in recovery

Method of measurement

Modified aldrete score

4

Description

Average of pain intensity

Timepoint

The first 24 hour after surgery

Method of measurement

visual analog scale

5

Description

Average time of extubation

Timepoint

After surgery

Method of measurement

Minute

Intervention groups

1

Description

Intervention group: they receive 0/1 mg per kg ondansetron in 10 cc normal saline in 10 minute

Category

Prevention

2

Description

Control group: 10 cc normal saline in 10 minute

Category

Placebo

3

Description

Intervention group: they receive 1 microgram per kilogram in 10 cc normal saline in 10 minute

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Seyed Mohammad Reza Safavi Hommami

Street address

Shahid Keshvari Highway, Soufe Boulevard

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Phone

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2

Recruitment center

Name of recruitment center

Ayatollah kashani hospital

Full name of responsible person

Seyed Mohammad Reza Safavi Hommami

Street address

Kashani Street, between Taleghani Street and Mirdamad Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Siavash

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

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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

Seyed Mohammadreza Safavi Homami

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Seyed Mohammadreza Safavi Homami

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

Negar Maleki

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available