Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Ondansetron vs Haloperidol to prevent postoperative nausea and vomiting in patients undergoing surgery with general anesthesia

Protocol summary

Study aim

Determining the effect of ondansetron with haloperidol in reducing postoperative nausea and vomiting in patients undergoing general anesthesia in Islamic Azad University hospitals in 1400

Design

Clinical trial, with parallel groups, double-blind, simple randomized, phase 4 on 78 patients admitted to the hospitals of the Islamic Azad University from October 2021 to January 2022 .

Settings and conduct

The subjects will be selected from patients undergoing elective surgery with general anesthesia in the hospitals of the Islamic Azad University during the year 2021-2022 who meet the inclusion criteria to reach the desired sample size. Patients are divided into two simple randomized double-blind groups that are matched in terms of age, gender, and type of surgery.

Participants/Inclusion and exclusion criteria

Indication for general anesthesia Being in ASA 1,2 anesthesia class Possibility of patients follow up at least 24 hours after surgery Patient satisfaction to participate in this research project

Intervention groups

Intervention group 1: Ondansetron 4 mg intravenously is injected into the patients of this group 15 minutes before the end of the surgery. Intervention group 2 : At the same time, 1 mg of haloperidol is injected intravenously to the other group . All patients are evaluated for postoperative nausea and vomiting in recovery and after transfer to the ward during the first 24 hours after surgery .

Main outcome variables

Comparison of the effect of ondansetron and haloperidol on postoperative nausea in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210926052586N1**
Registration date: **2021-10-23, 1400/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-23, 1400/08/01**
Update count: **0**

Registration date

2021-10-23, 1400/08/01

Registrant information

Name

Seyedmohammad Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 6660

Email address

smkarimi.md@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Ondansetron vs Haloperidol to prevent postoperative nausea and vomiting in patients undergoing surgery with general anesthesia

Public title
Comparison of Ondansetron vs Haloperidol to prevent postoperative nausea and vomiting

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General anesthesia indication ASA 1,2 class Possibility of patient follow up at least 24h after surgery Patient satisfaction to participate in this research project

Exclusion criteria:
Advanced underlying disease Addiction Patient dissatisfaction to participate in this research project Motion Sickness Excessive bleeding during surgery Severe postoperative complication BMI>30

Age
No age limit

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
The table of random numbers is prepared and by placing a hand on a number randomly and moving the hand in one of the predetermined directions, each person is given a number. People who have even numbers in will be in intervention group A and individual numbers will be in the group Intervention B.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and researchers remain unaware of how the drug is allocated during the study. The patient is informed that there are two types of drugs in a study and will take one of the two drugs at random. Both drugs are in the same package and have are no difference.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق در پژوهش دانشگاه علوم پزشکی آزاد اسلامی تهران

Street address
خیابان شریعتی، خیابان خاقانی، دانشگاه علوم پزشکی آزاد اسلامی واحد تهران

City
Tehran

Province
Tehran

Postal code
1949916656

Approval date
2021-08-03, 1400/05/12

Ethics committee reference number
IR.IAU.TMU.REC.1400.126

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting

ICD-10 code
K91.0

ICD-10 code description
تهوع و استفراغ بعد از عمل جراحی

Primary outcomes

1

Description
Comparison of the effect of ondansetron and haloperidol on postoperative nausea and vomiting

Timepoint
From recovery time to 24 hours after surgery

Method of measurement
Questionnaire number 1

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 15 mg of ondansetron is injected 15 minutes before the end of the surgery.

Category
Treatment - Drugs

2

Description
Intervention group: 15 mg of haloperidol is injected 15 minutes before the end of the surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
بیمارستان امیرالمومنین

Full name of responsible person
سید محمد کریمی

Street address
نازی آباد ، خ شیرمحمدی ، بیمارستان امیرالمومنین

City
Tehran

Province
Tehran

Postal code
1811694784

Phone
+98 21 5534 6550

Email
amhos@iautmu.ac.ir

Web page address
http://amhos.iautmu.ac.ir/fa/contactus

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
فرشاد هاشمیان

Street address
Tehran Islamic Azad University of Medical Sciences , Khaghani St, Shariati Ave

City
Tehran

Province
Tehran

Postal code
1916893813

Phone
+98 21 2200 6660

Email
chancellor@iautmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Seyedmohammad Karimi

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
Pabarja St , Sheidaei Ave , Darrous

City
Tehran

Province
Tehran

Postal code
1979999999

Phone
+98 21 2200 6660

Fax

Email
smkarimi.md@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Seyedmohammad Karimi

Position
Student

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Fax

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Person responsible for updating data

Contact

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Islamic Azad University

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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 more 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
Undecided - It is not yet known if there will be 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