Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effect of ondansetron and amisulpride on post operative nausea and vomiting (PONV) in general abdominal surgeries

Protocol summary

Study aim

Comparison of ondansetron and amisulpride effectiveness on post operative nausea and vomting (PONV) reduction in elective abdominal surgeries with general anesthesia.

Design

In this randomized double-blind clinical trial, 116 patients who meet the inclusion criteria will be randomized using randomized numbers table in two groups and the intervention and bias in patient selection will be minimized by the researcher.

Settings and conduct

The subjects will be selected from patients undergoing elective surgeries with general anesthesia in Azad University hospitals during 2020 and 2021. Then, the patients will be divided into two groups which are matched in terms of age, gender and type of surgery. In the first group, at half an hour before the ondansetron surgery, 4 mg and in the other group at the same time, amisulpride is injected intravenously.

Participants/Inclusion and exclusion criteria

Indication for general anesthesia Being in ASA 1,2 anesthesia class Patient satisfaction to participate in the study Possibility of follow-up within 24 hours of abdominal surgery 18.5<BMI<30 Advanced underlying disease Patient dissatisfaction to participate in the study Catching Motion sickness Excessive bleeding during surgery Severe postoperative complications

Intervention groups

The patients were divided into two groups that will be matched in terms of age, gender, type of surgery and type and method of general anesthesia. The first group will be injected intravenously with 4 mg of ondansetron within half an hour before the end of surgery and the other group will be injected 5 mg amisulpride intravenously. All patients will be evaluated for postoperative nausea and vomiting within 24 hours.

Main outcome variables

Ondansetron Amisulpride Gender Age BMI Post operative nausea and vomiting Stress Opioid

General information

Reason for update

Acronym

PONV

IRCT registration information

IRCT registration number: **IRCT20210926052599N1**
Registration date: **2021-10-19, 1400/07/27**
Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**
Update count: **0**

Registration date

2021-10-19, 1400/07/27

Registrant information

Name

Alireza Momennia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4262 4156

Email address

rudsar93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparison of the effect of ondansetron and amisulpride on post operative nausea and vomiting (PONV) in general abdominal surgeries

Public title
The comparison of the effect of ondansetron and amisulpride on post operative nausea and vomiting (PONV) in general abdominal surgeries

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Indication for general anesthesia Being in American Society of Anesthesiologists (ASA) 1,2 anesthesia class Patient satisfaction to participate in the study Possibility of follow-up within 24 hours after abdominal surgery 18.5< Body mass index (BMI) <30

Exclusion criteria:
Advanced underlying disease Patient dissatisfaction to participate in the study Catching Motion sickness Excessive bleeding during surgery Severe postoperative complications

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **116**

Randomization (investigator's opinion)
Randomized

Randomization description
Using random numbers table

Blinding (investigator's opinion)
Double blinded

Blinding description
After confirmation of this study by the university's research committee, patients who are candidates for elective abdominal surgery with general anesthesia are introduced to the researcher by the professor of anesthesia. On the night before surgery, in order to meet the inclusion criteria and brief description of the study for the patient to be informed of the patient and get written consent of attachment number two on the patient's bedside will be present. It is also explained to the individual that their absence in this study does not cause any problems in the routine process of their treatment and is completely optional. It is also explained to them that according to appendix 1 questionnaire, 24 hours after surgery, they will be revisited to fill out the questionnaire. Patients who meet the inclusion criteria based on the criteria will be randomized using random numbers table in two groups and control will be minimized by this method of involvement and bias in patient selection by the researcher. Patients themselves do not have the right to choose to be in the case or control group. In order to blind the study on the day of surgery, the operating room personnel are unaware of the type of injectable drug and at the time of injection, syringes of the same shape and color will be provided to the anesthetic technician who does not know the content of the syringes. Finally, after collecting data and analyzing the data, the results are compared between the two groups.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University of Tehran Medical Sciences

Street address
Islamic Azad university of Tehran medicine science, Zargandeh street, Shariati street

City
Tehran

Province
Tehran

Postal code
1949635881

Approval date
2021-02-24, 1399/12/06

Ethics committee reference number
IR.IAU.TMU.REC.1399.553

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description

Efficacy of medication on postoperative nausea and vomiting

Timepoint

24 hours after surgery

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group will be injected intravenously at 5 mg of Amisulpride within half an hour before the surgery.

Category

Treatment - Drugs

2

Description

Control group: The second group will be injected intravenously with 4 mg of ondansetron within half an hour before the surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Buali hospital

Full name of responsible person

Dr Hosein Yahyavi

Street address

Buali hospital, Damavand street

City

Tehran

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1949635881

Phone

+98 21 2200 6666

Email

rudsar93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Amirmahyar Khoshsirat

Street address

Islamic Azad university of Tehran medicine sciences, Shariati street

City

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1949635881

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rudsar93@gmail.com

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

1

Public or private sector

Private

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

Alireaz Momennia

Position

intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No 11, behind of Shahid Ghasemi sport complex, Enghelab street

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4481833777

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Person responsible for scientific

inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Intern

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Person responsible for updating data

Contact

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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