Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of the effects of ginger, ondansetron and droperidol on nausea and vomiting after hysterectomy

Protocol summary

Study aim
Comparison of the effects of three drugs: ginger, ondansetron, and droperidol on nausea and vomiting after hysterectomy.

Design
The clinical trial included three groups of ondansetron, droperidol, and ginger, and each group included 25 participants in parallel groups, double-blind, randomized, phase 2 on a total of 75 patients. All eligible patients will be randomly assigned to the three mentioned groups by the random block method.

Settings and conduct
patients in the ginger group, one hour before the operation, receive 4 ginger capsules, each containing 250 mg of ginger, and 4 ml of distilled water added to the serum to equalize the form of the received drugs. People in the ondansetron group receive 8 mg of ondansetron and 4 placebo capsules in the droperidol group, 2.5 mg of droperidol, and 4 placebo capsules. The preparation of the drugs is done by the researcher to blind the clinical caregiver of the patient. Then, in the period of 2, 4, and 6 hours after the operation, the patient's nausea will measure by the vas scale and the number of the patient's vomiting will record.

Participants/Inclusion and exclusion criteria
Entry criteria include no cancer, no high blood pressure, age between 18-60 years, ability to swallow the capsules used in the study, platelet count above 100,000, no intestinal obstruction and hepatitis, no use of anti-nausea and vomiting drugs or drugs that cause it, no long-term treatment with corticosteroid drugs, and no history of ginger allergy, not using blood thinners and anticoagulants before the operation, and the exclusion criterion is the patient's unwillingness to continue the study.

Intervention groups
Ondansetron group, ginger group, droperidol group

Main outcome variables
Vomiting and the number of times the patient vomits are asked and recorded.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230128057257N1**
Registration date: **2023-02-05, 1401/11/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-05, 1401/11/16**
Update count: **0**

Registration date
2023-02-05, 1401/11/16

Registrant information

Name
Reza Latifi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3412 0065

Email address
dr.r.latifi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-31, 1401/11/11

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effects of ginger, ondansetron and droperidol on nausea and vomiting after hysterectomy

Public title
Comparison of the effects of ginger, ondansetron and droperidol on nausea and vomiting after hysterectomy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for hysterectomy surgery Willingness to participate in the study after obtaining informed consent Age between 18-60 years The ability to swallow the capsules used in the study Platelet count above 100000

Exclusion criteria:
Having cancer Hypertension Intestinal obstruction and hepatitis Taking anti-nausea and vomiting drugs or drugs that cause it Long-term treatment with corticosteroid drugs Ginger allergy history Use of blood thinners and anticoagulants before surgery

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
All patients with the entry criteria will be divided into three equal groups using a randomized block method; for each of the patients, the drugs studied in three groups were prepared by the anesthesiologist and they were prepared in the form of syringes of the same shape and color and with the same volume, and only 1-2-3 labels were placed on them. Then it will be given to the anesthetist technician of the project (who does not know the type of drugs) to be injected into the patients, also the patients do not know the type of drugs received. Additionally, the intern in charge of the project, who is responsible for completing the project questionnaires after the surgery, is also not aware of the type of study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind study. Blinding of the participants was done using the same appearance of the drugs. Also, the patients did not have any information about which group they were assigned to. The blinding of the researcher was also done in such a way that one person delivered the medicine to a patient who did not know its type.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2022-12-11, 1401/09/20

Ethics committee reference number
IR.ARAKMU.REC.1401.276

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The amount of nausea and vomiting after surgery

Timepoint
2, 4, and 6 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: ondansetron, one hour before

surgery, 8 mg of ondansetron by injection

Category

Prevention

2

Description

Intervention group: droperidol, one hour before surgery, 2.5 mg droperidol injection

Category

Prevention

3

Description

Intervention group: Ginger, one hour before the operation, 4 ginger capsules, each containing 250 mg of ginger.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Educational and Therapeutic Center

Full name of responsible person

Maryam Shokrpour

Street address

Taleghani Educational Medical Center, West Imam Khomeini Street

City

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Postal code

3816149369

Phone

+98 86 3277 6063

Email

maryam_shokrpour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

mehdi salehi

Street address

Research and Technology Vice-Chancellor, University complex of the Prophet (PBUH), Basij Square (Sardasht)

City

Arak

Province

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3848176341

Phone

+98 86 3417 3639

Email

salehi58@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Reza Latifi

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Maryam Shokrpour

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
In order to protect the privacy and personal information of the patient, the non-disclosure of personal information and other such information is mentioned in the informed consent form to obtain the consent of the patient and her family.

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