Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of ginger and dexamethasone and ondansetron and promethazine in reducing postoperative nausea and vomiting in patients undergoing hysterectomy

Protocol summary

Study aim
Comparison of the effects of ginger and dexamethasone and ondansetron and promethazine in reducing postoperative nausea and vomiting in patients undergoing hysterectomy

Design
The study will be double blind and clinical trial.100 patients will be randomly divide into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct
Patients who are candidates for hysterectomy at Sina Rezaei Ashtiani Hospital in Arak are divided into 4 groups using simple randomization with the envelope method. The study is double-blind, and blinding of the analyzer, outcome evaluator, and participant is performed.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: no history of cancer, no history of high blood pressure, 40 to 60 years, platelet count above 100000, no history of intestinal obstruction and hepatitis, no use of anti-nausea and anti-vomiting drugs or drugs that induce them, no long-term treatment with corticosteroid drugs, no history of allergy to ginger Exclusion Criteria: lack of patient's consent to participate in the study, willingness to cooperate, patients who experience cardiopulmonary arrest during surgery

Intervention groups
Intervention Groups: Ginger Group:patients in the ginger group receive two 500 miligeram Vomegan Dineh ginger tablets, each containing 500 mg of ginger, one hour before the surgery. To standardize the appearance of the received medications, they also receive 4 millileter of distilled water in a serum. Ondansetron Group: patients in the ondansetron group receive 8 miligeram of ondansetron. Dexamethasone Group: patients receive 8 miligeram of dexamethasone intravenously before anesthesia induction. Promethazine Group:Patients receive 6.25 miligeram of promethazine intravenously before anesthesia induction.

Main outcome variables
Nausea, vomiting, sedation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N201**
Registration date: **2025-11-17, 1404/08/26**
Registration timing: **prospective**

Last update: **2025-11-17, 1404/08/26**
Update count: **0**

Registration date
2025-11-17, 1404/08/26

Registrant information

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Name of organization / entity
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01

Expected recruitment end date
2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of ginger and dexamethasone and ondansetron and promethazine in reducing postoperative nausea and vomiting in patients undergoing hysterectomy

Public title

Comparison of the effects of ginger and dexamethasone and ondansetron and promethazine in reducing postoperative nausea and vomiting in patients undergoing hysterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No history of cancer No history of high blood pressure Age between 40 to 60 years Ability to swallow the pill used in the study Platelet count above 100000, no history of intestinal obstruction and hepatitis No use of anti-nausea and anti-vomiting drugs or drugs that induce them No history of allergy to ginger No use of blood-thinning and anticoagulant drugs before surgery

Exclusion criteria:

Lack of patient's consent to participate in the study Willingness to cooperate Patients who experience cardiopulmonary arrest during surgery Patients who are referred to the intensive care unit for any reason

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into4 groups using a permuted balanced block randomization method with the size of blocks8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Random chain concealment is done by opaque envelope method

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. The analysis is done by the analyst and outcome evaluator (double-blind) and the participant. The analyst, evaluator, and participant are unaware of the consequences of grouping. The patients under study, as well as all project staff, including surgeons, anesthesia technicians, scrub nurses, and interns, will be unaware of how patients are assigned to the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Arak University of Medical Sciences

Street address

Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2025-10-19, 1404/07/27

Ethics committee reference number

IR.ARAKMU.REC.1404.273

Health conditions studied

1

Description of health condition studied

Hysterectomy

ICD-10 code

N99.3

ICD-10 code description

Prolapse of vaginal vault after hysterectomy

Primary outcomes

1

Description

Incidence of nausea

Timepoint

Recovery and 2, 4, 6, 12 and 24 hours after surgery

Method of measurement

Observation

2

Description

Vomiting

Timepoint
Recovery and 2, 4, 6, 12 and 24 hours after surgery
Method of measurement
Score 0 to 4

3

Description
Sedation
Timepoint
In recovery and 1, 2 and 4 hours after surgery
Method of measurement
Ramsay score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Patients in the ginger group receive two 500 mg Vomegan Dineh ginger tablets (manufactured by Dineh Bern Company), each containing 500 mg of ginger, one hour before the surgery. To standardize the appearance of the received medications, they also receive 4 ml of distilled water in a serum.
Category
Treatment - Drugs

2

Description
Intervention group2: Patients in the ondansetron group receive 8 mg of ondansetron (manufactured by Alborz Darou Pharmaceutical Company).
Category
Treatment - Drugs

3

Description
Intervention group3: Patients receive 8 mg of dexamethasone (manufactured by Alborz Darou Pharmaceutical Company) intravenously before anesthesia induction.Promethazine Group:
Category
Treatment - Drugs

4

Description
Intervention group4: Patients receive 6.25 mg of promethazine (manufactured by Alborz Darou Pharmaceutical Company) intravenously before anesthesia induction.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Dr Alireza Kamali
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Sponsors / Funding sources

1

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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
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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