Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of the prophylactic effect of dexamethasone and droperidol in comparison with dexamethasone and ginger on nausea and vomiting in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim
Evaluation of the prophylactic effect of dexamethasone and droperidol in comparison with dexamethasone and ginger on nausea and vomiting in patients undergoing laparoscopic cholecystectomy

Design
Clinical trial, with two intervention and control groups, double-blind, with a sample size of 152, using the block randomization method with blocks of size 8.

Settings and conduct
This study will be conducted in Valiasr Hospital of Arak and on patients who will be candidates for cholecystectomy. The plan will be implemented in a double-blind manner. In this study, the patients do not know about the medicine received. To comply with the blinding, the medicines are prepared by the anesthesiologist in the same syringes and labels 1 and 2 will be placed on them, and then they will be given to the anesthesiologist for injection who won't know the intervention on each patient. Also the flour and ginger capsules will be prepared in the same way under the supervision of the anesthesiologist (in charge of the project) and will be given to the patients by the intern in charge of the project who is not aware of the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients who are candidates for elective laparoscopic cholecystectomy in Amirul Mominin and Valiasr Arak hospitals, who are under general anesthesia, age 65-18 years, ASA anesthesia class I, II, surgery duration between 60-150 minutes. Non-inclusion criteria: sensitivity to droperidol and ginger,

Intervention groups
Intervention: Dexamethasone 8 mg intravenously + droperidol 75 micrograms/kg intravenously + 4 capsules of flour. Control: Dexamethasone 8 mg intravenously + 4 oral ginger capsules + syringe containing distilled water

Main outcome variables
Nausea, vomiting, chills

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230506058101N1**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date
2023-05-31, 1402/03/10

Registrant information

Name
Atefeh Mozzafaryjalal

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3313 6055

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mozafaryatefeh1@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-10, 1402/03/20

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the prophylactic effect of dexamethasone and droperidol in comparison with dexamethasone and ginger on nausea and vomiting in patients undergoing laparoscopic cholecystectomy

Public title
The effect of dexamethasone, droperidol and ginger on controlling nausea and vomiting

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Candidates for laparoscopic cholecystectomy who will be electively referred to Amir al-Momenin and Valiasr Arak hospitals Age range between 18-65 years ASA anesthesia class I, II Candidates for general anesthesia All candidate patients for laparoscopic cholecystectomy who undergo surgery Not being allergic to droperidol and ginger The duration of surgery between 60-150 minutes

Exclusion criteria:
Sensitivity to Droperidol and Ginger

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **152**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate the samples, the block randomization method with blocks of size 8 will be used. In this way, by using the software to generate random numbers using the block method and the randomization sequence, it will be produced according to the required sample size for the two groups. The two letters A and B can be arranged together in a block of size 8, and then a block is randomly selected from among the blocks, and the arrangement pattern in that block will be used to allocate the participants. Then this block in The original container will be placed and another block will be selected again. All these works will be done with a software called sealed envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to comply with blinding, firstly, the patients do not know the type of drug received, and after informed consent, they will enter the plan without knowing the type of drug received. In the droperidol group, the same capsule as the ginger capsule is used, in which flour is placed and will be given to the patient, and in the ginger group, a syringe identical to the droperidol syringe containing distilled water will be used. In order to comply with the blinding, the drugs will be prepared in advance by the anesthesiologist (project guide) in syringes of the same shape and labels 1 and 2 will be placed on them, and then they will be given to the anesthesiologist of the project for injection. The study does not know will be placed. Also, the flour and ginger capsules are prepared in the same way under the supervision of the anesthesiologist in charge of the project (supervisor) and will be given to the patients by the intern in charge of the project who does not know about the groups, so the project will be implemented in a double-blind manner. After the surgery, the project questions will be completed by the intern responsible for the project (he is not aware of the groups).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Arak University of Medical Sciences , Basij square

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2022-12-18, 1401/09/27

Ethics committee reference number
IR.ARAKMU.REC.1401.232

Health conditions studied

1

Description of health condition studied
cholecystitis

ICD-10 code
K81

ICD-10 code description
Cholecystitis

Primary outcomes

1

Description
Vomiting score during recovery
Timepoint
2, 4, 8 and 12 hours after surgery
Method of measurement
Vomiting scoring checklist

2

Description
Nausea
Timepoint
in post-operative recovery
Method of measurement
Ask the patient

3

Description
Shivering
Timepoint
in post-operative recovery
Method of measurement
Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In group A, 8 mg of intravenous dexamethasone and 75 µg/kg droperidol and 4 oral capsules of flour are given as a placebo instead of 4 oral ginger capsules before induction of anesthesia.
Category
Other

2

Description
Intervention group: In group B, patients receive 8 mg of intravenous dexamethasone and 4 ginger capsules orally and a syringe containing distilled water as a placebo instead of a syringe containing intravenous droperidol.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Arak hospital
Full name of responsible person
Atefeh Mozafary Jalal
Street address
Valiasr Arak hospital, Shahid Shiroudi street
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mehdi Salehi
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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

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Atefeh Mozafary Jalal

Position
student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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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