

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

Nausea, vomiting, chills

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

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)

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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 committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences , Basij square

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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

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Valiasr Arak hospital, Shahid Shiroudi street

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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 Mozafari Jalal

Position

student

Latest degree

Medical doctor

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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