Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The effect of dextrose injection in preventing postoperative nausea and vomiting in patients undergoing cholecystectomylaparoscopic surgery

Protocol summary

Study aim
The effect of dextrose injection in preventing postoperative nausea and vomiting in patients undergoing cholecystectomylaparoscopic surgery

Design
The study will be double blind and clinical trial.100 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

Settings and conduct
Patients candidate for cholecystectomylaparoscopic surgery in valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks.The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria:All candidates for laparoscopic cholecystectomy; age between 30 and 70 years; AqSA class I and II; patients under general anesthesia; the duration of surgery is between 60-150 minutes; absence of Parkinson's disease, motion sickness or history of chemotherapy; absence of diabetes Exclusion criteria:All patients who do not undergo general anesthesia for any reason; patients who suffer cardiac arrest during surgery; patients whose surgery lasts more than 180 minutes; patients who are referred to the intensive care unit for any reason

Intervention groups
Intervention group: will receive 10 millileter in kilogeram in hour of Ringer's lactate serum with 500 miligram in kilogeram of 5% dextrose. Control group: they will receive Ringer's lactate serum with 0.9% normal saline with the same volume as the intervention group. The solutions are infused 5 minutes before the induction of anesthesia until the end of the procedure.

Main outcome variables
Vomitting; nausea; Dose of metoclopramide in 24 hours

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N176**
Registration date: **2022-10-03, 1401/07/11**
Registration timing: **prospective**

Last update: **2022-10-03, 1401/07/11**
Update count: **0**

Registration date
2022-10-03, 1401/07/11

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 86 3222 2003

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-07, 1401/07/15

Expected recruitment end date
2023-10-07, 1402/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of dextrose injection in preventing postoperative nausea and vomiting in patients undergoing cholecystectomylaparoscopic surgery

Public title
The effect of dextrose injection in preventing postoperative nausea and vomiting in patients undergoing cholecystectomylaparoscopic surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All candidates for laparoscopic cholecystectomy Age between 30 and 70 years ASA class I and II Patients under general anesthesia The duration of surgery is between 60-150 minutes Absence of Parkinson's disease, motion sickness or history of chemotherapy Absence of diabetes

Exclusion criteria:
All patients who do not undergo general anesthesia for any reason. Patients who suffer cardiac arrest during surgery. Patients whose surgery lasts more than 180 minutes. Patients who are referred to the intensive care unit for any reason.

Age
From **30 years** old to **70 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 into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. 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 (two-blind) and the participant. Analysts, evaluators and participants are not aware of the consequences of grouping. The specialist assistant is unaware of the type of operation in each group and the surgeon is aware of the type of operation and patients are not aware of their group.

Placebo
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
2022-05-01, 1401/02/11

Ethics committee reference number
IR.ARAKMU.REC.1401.048

Health conditions studied

1

Description of health condition studied
Cholecystectomy laparoscopic surgery

ICD-10 code
K91.86

ICD-10 code description
Retained cholelithiasis following cholecystectomy

Primary outcomes

1

Description
Vomitting

Timepoint
In recovery, 2, 4, 6, 12 and 24 hours after the operation

Method of measurement
Score from 0 to 4 (no vomiting gets zero and frequent vomiting gets 4.)

2

Description
Severe nausea

Timepoint
Recovery, 2, 4, 6, 12 and 24 hours after the operation

Method of measurement
VAS visual analog scale

3

Description

Mean of dose of metoclopramide in 24 hours

Timepoint

At the end of the study

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 millileter in kilogeram in hour of Ringer's lactate serum along with 500 miligram in kilogeram of 5% dextrose will be given. The solutions are infused 5 minutes before induction of anesthesia until the end of the procedure.

Category

Treatment - Drugs

2

Description

Control group: they will receive Ringer's lactate serum with 0.9% normal saline with the same volume as the intervention group. The solutions are infused 5 minutes before the induction of anesthesia until the end of the procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Valiasr Hospital, Valiasr squre, Shahid Shirodi street

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3814957558

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mahmodie@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Valiasr Hospital, Valiasr squre, Shahid Shirodi street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Behnam Mahmodie

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohamad shafie

Position
medicine student

Latest degree
A Level or less

Other areas of specialty/work
Anesthesiology

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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