Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effect of Lidocaine and Granisetron on postoperative nausea and vomiting in laparoscopic cholecystectomy

Protocol summary

Study aim
Comparison of the effect of lidocaine and granisetron on nausea and vomiting after laparoscopic cholecystectomy

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 120 patients. Random allocation of samples to study groups is performed by block randomization method and by using R statistical software.

Settings and conduct
This double-blind clinical trial study will be performed on 120 patients undergoing laparoscopic cholecystectomy (in three groups of intervention 1, intervention 2, and control) in Ayatollah Mousavi Hospital in Zanjan. Random allocation of samples is perform by block method and using statistical software.Visual analog scale (VAS), Rhodes questionnaire and demographic information questionnaire will be used to assess the incidence and severity of postoperative nausea and vomiting.Questionnaires are completed by the researcher during the operation and at certain hours (recovery, 6, 12 and 24 hours after the operation).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age>18 years, American Society of Anesthesiologists Class (ASA Class) I & II, No history of motion sickness, No history of drug allergy, Laparoscopic cholecystectomy under general anesthesia, Body Mass Index<30, Non-smoking, Not receiving anti-nausea medication in the last 24 hours

Intervention groups
Patients in intervention group 1, at the end of the surgery (after discontinuation of anesthetic drugs) and before extubation, receiving 1.5 mg/kg of lidocain 2% (manufactured by Caspian Tamin Company) intravenously.Patients in intervention group 2, at the end of the surgery (after discontinuation of anesthetic drugs) and before extubation, receiving 3 mg of Granisetron (manufactured by Caspian Tamin Company) intravenously.Patients in control group dosn't receive medication.

Main outcome variables
Postoperative nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200910048678N1**
Registration date: **2020-12-01, 1399/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-01, 1399/09/11**
Update count: **0**

Registration date
2020-12-01, 1399/09/11

Registrant information

Name
seyede fatemeh gheiasi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 24 3314 8338

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fatemeh.gheiasi@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-19, 1399/06/29

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Lidocaine and Granisetron on postoperative nausea and vomiting in laparoscopic cholecystectomy

Public title

Comparison of the effect of Lidocaine and Granisetron on postoperative nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age>18 year American Society of Anesthesiologists Class (ASA Class) I & II No history of motion sickness No history of drug allergy Laparoscopic cholecystectomy under general anesthesia Body Mass Index (BMI) <30 Non-smoking Not receiving anti-nausea medication in the last 24 hours

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of samples to study groups is done by block randomization method within a block size of 4. To be more accurate, block randomization is performed by using R statistical software and is provided for the researcher who is responsible for collecting samples, and participants are divided into three groups based on the code assigned to each treatment (A, B, C) without researcher's interference.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients know they are participating in a study that is aimed to evaluate the effect of Lidocaine and Granistrone on the treatment of postoperative nausea and vomiting but they are not informed that they receive Lidocaine or Granistrone or not receive any medication. Drugs are coded and the anesthesiologist who injects the drug are not aware of the medication that patients receive.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Vice-Chancellor for Research and Technology, 3th Floor, 2th Bldg., Zanjan University of Medical Sciences, Azadi Blvd. Zanjan, IRAN.

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-09-08, 1399/06/18

Ethics committee reference number

IR.ZUMS.REC.1399.226

Health conditions studied

1

Description of health condition studied

Cholecystitis

ICD-10 code

K81.9

ICD-10 code description

Cholecystitis, unspecified

Primary outcomes

1

Description

Postoperative nausea

Timepoint

Recovery, 6, 12 and 24 hours after surgery

Method of measurement

Rhodes Questionnaire, Visual Analogue Scale

2

Description

Postoperative vomiting

Timepoint

Recovery, 6, 12 and 24 hours after surgery

Method of measurement

Rhodes Questionnaire, Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Patients in intervention group 1, at the end of the surgery (after discontinuation of anesthetic drugs) and before extubation, receiving 1.5 mg/kg of lidocain 2% (manufactured by Caspian Tamin Company) intravenously.
Category
Treatment - Drugs

2

Description
Patients in intervention group 2, at the end of the surgery (after discontinuation of anesthetic drugs) and before extubation, receiving 3 mg of Granisetron (manufactured by Caspian Tamin Company) intravenously.
Category
Treatment - Drugs

3

Description
Control group: They do not receive any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Seyede Fatemeh Gheiasi
Street address
Ayatollah Mousavi Educational and Medical Center, Gavazang, Zanjan, IRAN.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Alireza Shoghli
Street address
Vice-Chancellor for Research and Technology, 3th Floor, 2th Bldg., Zanjan University of Medical Sciences, Azadi Blvd. Zanjan, IRAN.
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research@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Seyede Fatemeh Gheiasi
Position
Educational staff
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Not applicable

Title and more details about the data/document
There is no more information.

When the data will become available and for how long
There is no more information.

To whom data/document is available
There is no more information.

Under which criteria data/document could be used
There is no more information.

From where data/document is obtainable
There is no more information.

What processes are involved for a request to access data/document
There is no more information.

Comments