

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of IV dextrose 5% on incidence of postoperative nausea and vomiting after laparoscopic cholecystectomy

Protocol summary

Summary

The aim of this randomized, double-blind clinical trial is to evaluate the effect of dextrose on nausea and vomiting after laparoscopic cholecystectomy surgery in the operating room of Imam Khomeini hospital of Sari. A total 132 patients with inclusion criteria are randomized into two 66 equal groups. After establishment of monitoring of the operating room, all patients will be placed under general anesthesia with the same anesthetic technique, including midazolam 0.01 mg / kg, fentanyl 2µg / kg for Pre-medication, Propofol 2-2.5 mg / kg, cisatracurium 0.15 mg / kg for induction of anesthesia and isoflurane 1-1.5 MAC, morphine 0.1 mg / kg and 0.0 2 mg / kg cisatracurium during maintenance of anesthesia. Intravenous fluid will be standardized 3cc / kg / hr for all patients during surgery. Level of blood glucose will be measured before the start of the infusion of study solution, half an hour after the start of operation and at the beginning of the recovery with glucometer . Patients in the intervention group will receive half a liter of solution containing 5% dextrose in Ringer Lactate (Add 25 ml 50% dextrose in half a liter of Ringer lactate) and the control group will receive a half liters of ringer lactate solution. Nausea and vomiting will be asked and recorded according to the VRS, immediately and then at 30, 60, 90, 120 after recovery and then at 6, 12, 24 hours after being discharged from the recovery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504086803N9**
Registration date: **2015-05-27, 1394/03/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-27, 1394/03/06

Registrant information

Name

Abolfazl Firouzian

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2014-05-31, 1393/03/10

Expected recruitment end date

2015-05-31, 1394/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of IV dextrose 5% on incidence of postoperative nausea and vomiting after laparoscopic cholecystectomy

Public title

Effect of IV Dextrose on postoperative nausea and vomiting after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: (1) the desire to participate in the study, and informed consent(2) planned laparoscopic cholecystectomy surgery (3) age between 18-65 years. Exclusion criteria included: (1) At any time based on the patient's unwillingness to continue participating in study (2) Systemic hypertension (blood pressure above the 140/90 mm-Hg in two or more measurements)(3) renal failure(4) coagulopathy (5)chronic heart failure, (6)liver failure(7) Diabetes mellitus (fasting morning glucose levels over 100 mg / dl)(8) previous history of severe nausea and vomiting after surgery (9)pregnancy(10) surgery prolonged more than 2 hours.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

sari

Postal code

4817844718

Approval date

2014-11-25, 1393/09/04

Ethics committee reference number

28/8/1393

Health conditions studied

1

Description of health condition studied

postoperative nausea and vomiting after laparoscopic cholecystectomy

ICD-10 code

k91.0

ICD-10 code description

Vomiting following gastrointestinal surgery

Primary outcomes

1

Description

incidence of nausea and vomiting

Timepoint

immediately and at 30, 60, 90, 120 after recovery and at 6, 12, 24 hours after being discharged from the recovery

Method of measurement

yes/no and Record in Questionnaire

Secondary outcomes

1

Description

intensity of nausea and vomiting

Timepoint

immediately and at 30, 60, 90, 120 after recovery and at 6, 12, 24 hours after being discharged from the recovery

Method of measurement

VRS(visual rating scale) and Record in Questionnaire

2

Description

use of antiemetics

Timepoint

during 24 hours after surgery

Method of measurement

mg(miligram) and record in questionnaire

Intervention groups

1

Description

infusion of 500cc solution containing 5% dextrose in Ringer Lactate within 30 minutes before induction of anesthesia

Category

Treatment - Drugs

2

Description

infusion of 500cc solution containing Ringer Lactate within 30 minutes and before induction of anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospita

Full name of responsible person

Abolfazl Firouzian MD, Assistant Professor

Street address

Emam Khomeini Hospital, Amir mazandarani Ave.

City

sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Mazandaran University of Medical Sciences, Moallem Square.

City

SARI

Grant name

10506

Grant code / Reference number

28/8/1393

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Abolfazl Firouzian MD

Position

Anesthesiologist, Assistant Professor

Other areas of specialty/work

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Other areas of specialty/work

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty