

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of intravenous diphenhydramine injection before anesthesia induction on postoperative pain , nausea and vomiting reduction in bariatric laparoscopic surgery

Protocol summary

Study aim

Determining the effect of intravenous diphenhydramine on pain reduction after bariatric surgery in recovery and ward

Design

A double-blind randomized clinical trial with control group, and parallel groups, phase 3-2 on 38 patients. Excel software was used to randomize.

Settings and conduct

A double blind clinical trial study in obese patients with a body mass index greater than 40 was performed at Sinai Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All obese patients are candidates for bariatric surgery aged 20-55 years Exclusion criteria: history of large prostate disease, glaucoma, uncontrolled blood pressure

Intervention groups

Intervention group: 0.5 mg/kg of diphenhydramine is injected intravenously before anesthesia induction and the degree of agitation, pain, and hemodynamic changes during extubation, and the incidence of nausea and vomiting in the recovery and the total amount of analgesic requirement are evaluated during 24 hours after surgery. Control group: They do not receive medication and the degree of agitation, pain, and hemodynamic changes during extubation, and the incidence of nausea and vomiting in the recovery and the total amount of analgesic requirement are evaluated during 24 hours after surgery.

Main outcome variables

The incidence of pain, agitation, nausea, and vomiting after bariatric surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130304012695N6**

Registration date: **2020-07-10, 1399/04/20**

Registration timing: **retrospective**

Last update: **2020-07-10, 1399/04/20**

Update count: **0**

Registration date

2020-07-10, 1399/04/20

Registrant information

Name

mohammadreza khajavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1220

Email address

khajavim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-14, 1398/01/25

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

2019-04-09, 1398/01/20

Actual recruitment end date

2020-07-02, 1399/04/12

Trial completion date

2020-07-05, 1399/04/15

Scientific title

Evaluation of the effect of intravenous diphenhydramine

injection before anesthesia induction on postoperative pain , nausea and vomiting reduction in bariatric laparoscopic surgery

Public title

Reduction of nausea ,vomiting and pain of bariatric surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Body mass index grater than 40

Exclusion criteria:

History of large prostate disease Glucome Drug addiction uncontrolled hyperthension

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **38**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize patients with inclusion criteria Block balanced randomization is used.Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms four blocks for the intervention and control group. The complete cards of the four blocks are given to the head of the operating room, who is unaware of the study, in an envelope. A card is given to the patient after patient entrance to operating room.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants:Since patients are not aware of the type of study drug at the time of anesthesia induction they were blind about the group to which they were allocated. Those who evaluate the outcome:The assistant who records the results in this study does not know the type of group Data collection officials:The person who analyzes the data also does not know the type of participating groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of school of medicine, Tehran university of medical scieences

Street address

Sina hospital,Hasan Abad Sq-Emam khomeni st.

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2019-03-04, 1397/12/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.958

Health conditions studied

1

Description of health condition studied

Abdominal Acute Pain after laparoscopic bariatric surgery

ICD-10 code

R10.0

ICD-10 code description

Acute abdomen

2

Description of health condition studied

Postoperative nausea and vomiting

ICD-10 code

K 91.0

ICD-10 code description

Vomiting following gastrointestinal surgery

Primary outcomes

1

Description

Incidence and severity of abdominal pain

Timepoint

During extubation and 5, 15, 30 and 60 minutes after surgery

Method of measurement

Visual Analogue Scale

2

Description

Severity of postoperative agitation

Timepoint

During extubation and 5, 15, 30 and 60 minutes after surgery

Method of measurement

Ramsy sedation Scale

3

Description

Incidence of nausea and vomiting

Timepoint

In recovery room and ward

Method of measurement

The number of nausea and vomiting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 0.5 mg/kg of diphenhydramine is injected intravenously before anesthesia and the degree of agitation, pain, and hemodynamic changes during extubation, and the incidence and severity of abdominal pain and nausea and vomiting in the recovery and the total amount of analgesic requirement are evaluated during 24 hours after surgery.

Category

Prevention

2

Description

Control group: They do not receive medication and the degree of agitation, pain, and hemodynamic changes during extubation, and the incidence and severity of abdominal pain and nausea and vomiting in the recovery and the total amount of analgesic requirement are evaluated during 24 hours after surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Mohammad Reza Khajavi

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Sina Hospital Imam khomeini st

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Keshavarz Blvd., corner of Quds St., Central Organizational University of Medical Sciences of Tehran

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khajavi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

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

Yes - There is a plan to make this available

Title and more details about the data/document

All information used for this research can be shared after unidentified the identity of patients. Also, statistical information, information analysis, study method, findings and conclusions can be shared.

When the data will become available and for how long

Starting access after accepting by a valid scientific journal and publishing it

To whom data/document is available

For academic researchers and in the field of science

Under which criteria data/document could be used

All researchers can use all published material and if all or part of this research is published by other people, the name and source of this research and its researchers should be mentioned.

From where data/document is obtainable

Mohammad Reza Khajavi

What processes are involved for a request to access data/document

The applicant can request the type of files by email.
khajavim@tums.ac.ir

Comments