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)

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+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 sciecences
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

Street address

Sina Hospital Imam khomeini st

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Tehran

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khajavim@tums.ac.ir

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 Organizatioehran 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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Tehran University of Medical Sciences
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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