Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determining the effect of a combination of Promethazine, Dexamethasone, and Ondansetron in comparison with Haloperidol, Dexamethasone, Ondansetron for prophylaxis of nausea and vomiting after laparoscopic bariatric surgery in Sina hospital, 2018.

Protocol summary

Study aim
Comparing antiemetic effect of Promethazine, Dexamethasone, Ondansetron and Haloperidol, Dexamethazone, Ondansetron after laparoscpoic bariatric surgery.

Design
This is a two arm parallel double blind clinical trial. The participants are selected from patients aged 18-65 years who are candidates for laparoscopic bariatric surgery and have the inclusion criteria. Eighty patients are divided to two equal groups through simple randomization using a random number table. Group A receives a three-drug regimen (Ondansetron 4 mg, Dexamethasone 8 mg and Haloperidol 2 mg) and group B receives Ondansetron 4 mg, Dexamethasone 8 mg and Promethazine 25 mg for PONV prophylaxis.

Settings and conduct
This is a randomized two arm parallel double blind clinical trial in Sina hospital.Patients and researcher are not informed of each patient's intervention group. Post operative follow up is done by researcher who knows the patient's names but not the antiemetic used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Age 18-65 years • BMI>30 Kg/m2 • ASA class I or II Exclusion criteria: • Contraindication to dexamethasone, ondansetron, haloperidol, and promethazine • Use of illicit drugs, hormonal anti-inflammatory drugs, and antiemetics within 24 hours before surgery • Serious adverse reaction like shock, cardiac arrest, and hemorrhage requiring transfusion • History of prolonged QT

Intervention groups
Group A receives a three-drug regimen (Ondansetron 4 mg, Dexamethasone 8 mg and Haloperidol 2 mg) and group B receives Ondansetron 4 mg, Dexamethasone 8 mg and Promethazine 25 mg.

Main outcome variables
Post operative nausea and vomiting score at recovery room, 6 and 24 hours after surgery, First time of antiemetic prescription after surgery until 24 hours, Accumulative dose of antiemetics prescription after surgery until 24 hours, Recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170805035510N3**
Registration date: **2018-06-22, 1397/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-22, 1397/04/01**
Update count: **0**

Registration date
2018-06-22, 1397/04/01

Registrant information

Name
Pejman Pourfakhr

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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+98 21 4466 3963

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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2018-03-06, 1396/12/15
Expected recruitment end date
2019-02-19, 1397/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the effect of a combination of Promethazine, Dexamethasone, and Ondansetron in comparison with Haloperidol, Dexamethasone, Ondansetron for prophylaxis of nausea and vomiting after laparoscopic bariatric surgery in Sina hospital, 2018.

Public title
Comparing the effect of a combination of Promethazine, Dexamethasone, Ondansetron in comparison with Haloperidol, Dexamethasone, Ondansetron for prophylaxis of nausea and vomiting after bariatric surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
• Age 18-65 years • BMI>30 • ASA class I or II • At least 2 risk factors for postoperative nausea and vomiting according to the Apfel criteria
Exclusion criteria:
• Contraindication to Dexamethasone, Ondansetron, Haloperidol, and Promethazine • Use of illegal drugs, hormonal anti-inflammatory drugs, and antiemetics within 24 hours before surgery • Serious adverse reaction like shock, cardiac arrest, and hemorrhage requiring transfusion • Pregnancy and lactation • Psychiatric diseases treated with antipsychotics • History of migraines • Cardiac pacemaker • History of prolonged QT
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
This is randomized double blind clinical trial.80 patients were assigned in two group of 40 people according to random numbers.Patients and researcher have no data of this randomization.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is double blind clinical trial.Patients and researcher are not informed of randomization. Questionnaire designed in three pages; Page 1 including patients' name and group (A or B) which is selected by randomization,is recorded at operation room by Anesthetic technician.On the next pages which include demogarphic and post operative data, only patients' name is recorded. Pages 2 and 3 will be filled in by researcher who doesn't know patients' group. Page 1 will be kept in a separate folder and pages 2 and 3 will be kept together in another folder. Finally, we'll open the two folders and sort the pages according to pharmacological groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences and Health services
Street address
Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2016-11-22, 1395/09/02
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.1085

Health conditions studied

1

Description of health condition studied
post operative nausea and vomiting after Bariatric surgery
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Post operative nausea and vomiting score
Timepoint
Recovery room,6hours after surgery,24hours after surgery
Method of measurement
NVRS(Nausea Verbal Rating Scale)

2

Description
First time of antiemetic prescription after surgery
Timepoint
Until 24hours after surgery
Method of measurement
according to physician's orders and nursing notes

3

Description
accumulative dose of antiemetics prescription after surgery
Timepoint
24hours after surgery ended
Method of measurement
according to recorded physician's orders and nursing notes

4

Description
recovery time
Timepoint
Until discharge of recovery room
Method of measurement
According to medical records

Secondary outcomes

1

Description
Post operative adverse effects
Timepoint
Until 24 hours after surgery
Method of measurement
Occurrence of Life threatening complications or annoying complaints for patients

2

Description
Accumulative dose of prescribed narcotics
Timepoint
6 hours and 24 hours after surgery
Method of measurement
according to physician's orders and nursing note

3

Description
post operative pain score
Timepoint
recovery room,6hours after surgery,24hours after surgery
Method of measurement
patients rate pain severity according to tutored scale (0-10)

Intervention groups

1

Description
Group A receives a three-drug regimen (Ondansetron 4 mg, Dexamethasone 8 mg, and Haloperidol 2 mg) Patients receive Dexamethasone 8 mg after induction and at the beginning of surgery and Ondansetron 4 mg IV at the end of the operation and Haloperidol 2mg IM at the begining of surgery.
Category
Prevention

2

Description
Group B receives a different three-drug regimen (Ondansetron 4 mg, Dexamethasone 8 mg and Promethazine 25 mg) Patients receive Dexamethasone 8 mg after induction and at the beginning of surgery, Ondansetron 4 mg IV at the end of the surgery and Promethaizine 25 mg IM 30 minutes before extubation.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Pejman Pourfakhr
Street address
Sina hospital, Hasan abad Square.
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Tehran
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Tehran
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1136746911
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pourfakhr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Pejman Pourfakhr
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pourfakhr@tums.ac.ir
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
Niusha Momeni
Position
Medical Student
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Niusha Momeni
Position
Medical student
Latest degree
Medical doctor
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