Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determination of effective dose of Dexamethasone and Promethazine in prophylaxis of post operative nausea and vomiting in patients undergoing laparoscopic anti-obesity operation: a clinical Trial.

Protocol summary

Summary

Objectives: Determination of effective dose of Dexamethasone and Promethasine in prophylaxis of post operative nausea and vomiting in patients undergoing laparoscopic anti-obesity operation. Design: In a post marketing phase of clinical trial (phase 3) or therapeutic uses 64 patients randomly divided into two groups. Inclusion/exclusion criteria: patients undergoing laparoscopic anti-obesity operation in Sina hospital (single center) with no contra-indication of receiving Dexamethasone and Promethasine. After induction of anesthesia, first group will receive 50 mg IV promethazin and 8 mg IV Dexamethasone and the second group will receive 25 mg IV promethazine and 4 mg IV Dexamethasone. Patients are asked about nausea severity and vomiting numbers every 12 hours for 48 hours after surgery, by other physicians who will be unaware about the group allocation. Primary and secondary outcome variables: the frequency of vomiting and nausea severity. (Based on VAS indicators will be asked from one to ten.)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510083773N15**
Registration date: **2016-09-20, 1395/06/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-20, 1395/06/30

Registrant information

Name

Farsad Imani

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 4469 0816

Email address

imanifar@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of effective dose of Dexamethasone and Promethazine in prophylaxis of post operative nausea and vomiting in patients undergoing laparoscopic anti-obesity operation: a clinical Trial.

Public title

Prophylaxis of post-operative nausea and vomiting after laparoscopic anti-obesity operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients from ASA class 1 and 2; Patients who are undergoing anti-obesity operation; Age in the range of 15-60 years. Exclusion criteria: Contraindications to receiving dexamethasone and promethazine; Uncontrolled diabetes or hypertension; Patients who have received anti-emetic drug in 24 hours ago.

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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 Science

Street address
Tehran University of Medical Science, Enqelab Street

City
Tehran

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
1394.856

Health conditions studied

1

Description of health condition studied
Prophylaxis of post-operative nausea and vomiting after laparoscopic anti-obesity operation

ICD-10 code
K91.1

ICD-10 code description
Postgastric surgery syndromes

Primary outcomes

1

Description
postoperative Nausea

Timepoint
12 hours after operation & 48 hours after operation

Method of measurement
Visual Analogue Scale

2

Description
postoperative vomiting

Timepoint
12 hours after operation & 48 hours after operation

Method of measurement
number

Secondary outcomes

empty

Intervention groups

1

Description
After induction of anesthesia, first group will receive 50 mg IV promethazine and 8 mg IV Dexamethasone

Category
Treatment - Drugs

2

Description
After induction of anesthesia, the second group will receive 25 mg IV promethazine and 4 mg IV Dexamethasone.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Dr.Naser Ghiasnejad Omrani

Street address
Sina Hospital, Imam khomeinyAve, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Dr. Naser Ghiasnejad Omran
Street address
Emam Khomeini St. Hasanabad Sq.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
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
Tehran University of Medical Science
Full name of responsible person
Dr.Naser Ghiasnejad Omran
Position
Resident
Other areas of specialty/work
Street address
Sina Hospital, Imam Khomeini Ave, Tehran
City
Tehran
Postal code
Phone
+98 216312000
Fax
Email
Naseromran@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Dr. Naser Ghiasnejad Omran
Position
Resident of Anesthesiology
Other areas of specialty/work
Street address
Sina Hospital, Imam Khomeini Ave, Tehran
City
Tehran
Postal code
Phone
+98 216312000
Fax
Email
Naseromran@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Dr.Farsad Imani
Position
Anesthetist, Medical Doctor
Other areas of specialty/work
Street address
Sina Hospital, Imam Khomeini Ave, Tehran
City
Tehran
Postal code
Phone
+98 21 63120
Fax
Email
imanifar@tums.ac.ir
Web page address

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