

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 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 Promethazine 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 Promethazine. After induction of anesthesia, first group will receive 50 mg IV promethazine 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

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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 Ghasnejad 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
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Resident

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Anesthetist, Medical Doctor

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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