

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation the effect of oral pregabalin on post operative pain after laparoscopic Gastric Bypass surgery

Protocol summary

Summary

Objectives: This study is aimed to compare the effect of oral pregabalin and placebo before surgery on post operative pain after laparoscopic Gastric Bypass surgery. Design: Prospective randomized clinical trial. Setting and conduct : Tertiary regional and teaching hospital. Participants including major eligibility criteria: Sixty patients, with age 18-50 yr; ASA Class I- II, undergoing laparoscopic Gastric Bypass surgery in Rasul Hospital during 2010-2011 , were included . Patients were randomized into two groups of 30 each, using a table of random numbers. Intervention: Study group , patients received 300 milligrams pregabalin and control group patients received 300 milligrams placebo within one hour before surgery. Main outcome measures (variables): VAS and PONV. The medications are coded and delivered to the patients by and individual not aware of the research process. A blind stuff assessed VAS and PONV in each groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102255184N2**
Registration date: **2012-01-28, 1390/11/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-28, 1390/11/08

Registrant information

Name

Seyede Fateme Navadegi

Name of organization / entity

Tehran University of Medical Sciences and Health

Services

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2009-08-30, 1388/06/08

Expected recruitment end date

2011-09-06, 1390/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of oral pregabalin on post operative pain after laparoscopic Gastric Bypass surgery

Public title

Effect of oral pregabalin on post operative pain after laparoscopic Gastric Bypass surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-50 yr; ASA Class I- II Exclusion criteria: Systolic Blood pressure less than 90 mmHg; Substance abuse; Pregnancy and breast feeding; Nonsteroidal anti-inflammatory drugs sensitivity; Asthma and Allergic rhinitis, Peptic ulcer disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

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

Poursina Ave.

City

Tehran

Postal code**Approval date**

2010-02-01, 1388/11/12

Ethics committee reference number

43111

Health conditions studied**1****Description of health condition studied**

Postoperative pain control

ICD-10 code

G89.11

ICD-10 code description

Postoperative acute pain control

Primary outcomes**1****Description**

Pain score

Timepoint

At recovery, 30 minutes, 2,4,12 and 24 hours after

surgery

Method of measurement

VAS

Secondary outcomes**1****Description**

Opioid consumption

Timepoint

24 hours after surgery

Method of measurement

By PCA

2**Description**

Nausea & vomiting

Timepoint

24 hours after surgery

Method of measurement

By asking the patient the question

Intervention groups**1****Description**

In the study group, 300 milligrams pregabalin, one hour before surgery

Category

Treatment - Drugs

2**Description**

In the control group, 300 milligrams placebo, one hour before surgery

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasul Hospital

Full name of responsible person

Mahzad Alimian

Street address

Satarkhan St.

City

Tehran

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences and Health Services

Full name of responsible person
Shahin Akhunzadeh MD.

Street address
Poursina St.

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences and Health Services

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
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Other areas of specialty/work

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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