Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 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

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Name of organization / entity

Tehran University of Medical Sciences and Health Services

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Iran (Islamic Republic of)

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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.
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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
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

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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