

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessing the effect of intraperitoneal marcaeine instillationin control of pain after laparoscopic sleeve gastrectomy

Protocol summary

Summary

Aim of this study is evaluation of intraperitoneal marcaeine effect in decreasing of pain after surgery.In this study patients with BMI more than 40 without exclusion criteria are entering in assessment.This survey is done randomized clinical trial.patients are allocated in two groups with balanced bloc randomization.In intervention group patients take 30 ml intraperitoneal marcaeine that instillate on spleen;stomach;diapheragm.Both groups take analgesic(1g every 6 hour intravenous acetaminophen&every 8 hour suppository diclofenac NA).Pain is recorded at 6&12&24 hours after operation with NRS questionnaire.Results between two groups are compared.Becuase no surgeon no patients know which one recieved intraperitoneal marcaeine when questionnare filling,study is double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120329181N4**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Nasser Malekpour Alamdari

Name of organization / entity

Shaid Behesht University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 4089

Email address

nassermalekpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shaid Beheshti Medical University;Tehran;Iran

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-10-23, 1395/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of intraperitoneal marcaeine instillationin control of pain after laparoscopic sleeve gastrectomy

Public title

Anti-pain effect assessment of intraperitoneal marcaeine after laparoscopic sleeve gastrectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria BMI more than 40 Exclusion criteria Untreatable cardiopulmonary disease;untreated addiction;untreated psychologic disorder

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: 120

Randomization (investigator's opinion)
Randomized

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 commity of Shahid Beheshti University of
Medicasl Sciences

Street address
Daneshju Avenue Velenjak

City
Tehran

Postal code

Approval date
2016-11-29, 1395/09/09

Ethics committee reference number
ir.sbm.u.retech.rec.1395.552

Health conditions studied

1

Description of health condition studied
Morbid Obesity

ICD-10 code
E66.8

ICD-10 code description
Other Obesity

Primary outcomes

1

Description
Pain

Timepoint
6,12.24 hour after operation

Method of measurement
Pain scaling criteria in NRS

2

Description

Hospital stay time

Timepoint
once

Method of measurement
Patient record

Secondary outcomes

1

Description
Nosocomial infection

Timepoint
First of study

Method of measurement
Report during 30 days

Intervention groups

1

Description
1g acetaminophen intravenous every 6 hour and
Diclofenac suppository every 8 hour in control group

Category
Treatment - Drugs

2

Description
30 cc Intraperitoneal marcaine instillation end of
operation and 1g Acetaminophen every 6 hour and
Diclofenac suppository every 8 hour in intervention
group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Modarres Hospital

Full name of responsible person
Nasser Malekpour Alamdari

Street address
Saadat Abad Modarres Hospital

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical sciences

Full name of responsible person
Nasser Malekpour Alamdari

Street address

Velenjak Daneshju avenue
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Shahid Beheshti University of Medical sciences
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
 Shahid Beheshti University of Medical Sciences
Full name of responsible person
 Nasser Malekpour Alamdari
Position
 Vascular Surgeon
Other areas of specialty/work
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 Modarres Hospital Saadat Abad
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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