Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Summary
Aim of this study is evaluation of intraperitoneal marcaine 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 marcaine 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 marcaine 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 laparascopic sleeve gastrectomy

Public title
Anti-pain effect assessment of intraperitoneal marcaine 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.sbmu.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 Sceinces

Full name of responsible person

Nasser Malekpour Alamdari

Position

Vascular Surgeon

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