Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Clinical trial examining the effect of the location of drains in abdominal pain after laparoscopy gastric bypass surgery Roux en y procedure in morbid obese

Protocol summary

Summary

The purpose of this study is to reduce pain after surgery for obesity.The patients with BMI> 40 or BMI> 35 with one comorbidity who are undergoing laparoscopic bypass surgery, are enrolled. Patients who convert to open or have activated drain, for any reason, so we must maintain the drain over 24 hours, are excluded from this study. We start this study in patients with morbid obesity who admitted in Rasool-e-Akram hospital. We select 50 patients. The intervention is that, At the end of the operation, when we have the negative result for air leak, in one group of patients Penrose drain was extracted from 5mm port in the left ant axillary line and in another groups through right midclavicular port. The Days after surgery leak test with methylene blue will performed.in Patients who haven't leak, the drain will be removed completely in the same day and will discharge and Patients with positive tests excluded from the study. The questionnaire for patients, including pain localization, severity of pain, positional association, relation to drain extraction site and other ports, the quality of pain and, etc. in 24 hours, 1 week and 1 month after the operation was filled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202198588N3**
Registration date: **2012-07-25, 1391/05/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-25, 1391/05/04

Registrant information

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Mohadeseh Pishgahroudsari
Name of organization / entity
Mnimally Invasive Surgery Research Center
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences.

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial examining the effect of the location of drains in abdominal pain after laparoscopy gastric bypass surgery Roux en y procedure in morbid obese

Public title

efficacy of Location of drains in abdominal pain after laparoscopic surgery for obesity.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Morbid obese patients with BMI over 40

or over 35 with one obese comorbidity such as metabolic disease, diabetes, HTN, HLP, Hyperbaric metabolic states;who are undergoing obesity surgery. Exclusion criteria: Patients who underwent laparoscopic surgery who converte to open؛Patients with activated drain for any reason(bleeding or Lake);The patients that forced us to maintain the drain for them over 24 hours.

Age
From **16 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.

City
Tehran

Postal code

Approval date
2012-04-24, 1391/02/05

Ethics committee reference number
51526

Health conditions studied

1

Description of health condition studied
post operative abdominal pain

ICD-10 code
R10.4

ICD-10 code description
Other and unspecified abdominal pain

Primary outcomes

1

Description
Abdominal Pain

Timepoint
24 hours after intervention, one week after internetion,1 month after intervention.

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Drain site infection

Timepoint
one week after intervention

Method of measurement
Clinical examination

2

Description
Small bowel herniation through drain extraction site

Timepoint
24 hours after intervention, 1 week after intervention, 1 month after intervention

Method of measurement
Clinical examination

Intervention groups

1

Description
The drain will be extracted from the right side of the patients.

Category
Prevention

2

Description
The drain will be extracted from the left side of the patients.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasool-e-Akram Hospital

Full name of responsible person

Street address
Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Teran University of Medical Sciences.
Full name of responsible person
Dr.Akbar Fotouhi
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Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Teran 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
Minimally Invasive Surgery Research Center, Tehran University of Medical Sciences.
Full name of responsible person
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Person responsible for updating data

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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