

# 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

##### Name

Mohadeseh Pishgahroudsari

##### Name of organization / entity

Minimally Invasive Surgery Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6655 5447

##### Email address

research@lapsurg.ir

#### 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 convert 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 intervention, 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

**Street address**  
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**  
Dr.Mohammad eidy

**Position**  
Fellowship of laparoscopy

**Other areas of specialty/work**

**Street address**  
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e-Akram Hospital, Niyayesh Ave, Sattarkhan St.,  
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## Person responsible for scientific inquiries

### Contact

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**Web page address**

## Person responsible for updating data

### Contact

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Mohadeseh pishgah-Roudsari

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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*