

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of abdominal pain after removing gallbladder through the umbilical and epigastric after gallbladder surgery

#### Protocol summary

##### Summary

The purpose of this study is the comparison of postoperative port site pain after removing the gallbladder from umbilical port site with epigastric port site in laparoscopic cholecystectomy. This study is performed on patients who are candidate for elective cholecystectomy in Rasool -e-Akram hospital and the patients who undergo laparoscopic cholecystectomy, are studied. The patients who their surgery convert to open, are excluded. The sample size is 148 cases who randomly divided into two groups. In the control group, the gallbladder is removed through epigastric port site as usual and in case group, it is removed through umbilical port site. Operations are performed by laparoscopic fellows with the supervision of laparoscopy attending surgeons or university professors and with minimal technical errors. The post operation pain is evaluated by using visual analog score pain score at 1,6,12 and 24 hours after surgery with expert research team who they don't know about site of gallbladder removal

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201207028588N10**

Registration date: **2012-10-20, 1391/07/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-10-20, 1391/07/29

##### 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

2012-10-06, 1391/07/15

##### Expected recruitment end date

2014-10-07, 1393/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of abdominal pain after removing gallbladder through the umbilical and epigastric after gallbladder surgery

##### Public title

Comparison of abdominal pain after gallbladder removal through two different areas

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Including criteria: the patients undergone laparoscopic cholecystectomy. Excluding criteria : The patients who their surgery convert to open.

##### Age

From **15 years** old to **90 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **150**

## 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, Keshavarz Blvd., Tehran, Iran.

##### City

Tehran

##### Postal code

#### Approval date

2012-09-26, 1391/07/05

#### Ethics committee reference number

65797

## Health conditions studied

### 1

#### Description of health condition studied

cholecystitis

#### ICD-10 code

K81

#### ICD-10 code description

Acute cholecystitis

### 2

#### Description of health condition studied

Cholelithiasis

#### ICD-10 code

K80

#### ICD-10 code description

Cholelithiasis

## Primary outcomes

### 1

#### Description

pain of epigastric port site

#### Timepoint

1 hour after intervention,6 hour after intervention,12 hour after intervention,24 hour after intervention,

#### Method of measurement

visual analog score

### 2

#### Description

pain of umbilical port site

#### Timepoint

1 hour after intervention,6 hour after intervention,12 hour after intervention,24 hour after intervention,

#### Method of measurement

visual analog score

## Secondary outcomes

### 1

#### Description

The patient's request for excessive analgesic during hospitalization

#### Timepoint

After intervention

#### Method of measurement

Read the patient records

### 2

#### Description

Duration of hospitalization

#### Timepoint

After intervention

#### Method of measurement

Read the patient records

## Intervention groups

### 1

#### Description

Removing the gallbladder from the epigastric port in the control group.

#### Category

Prevention

### 2

#### Description

Removing the gallbladder from the umbilical port in the case group

#### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

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**

Tehran University of Medical sciences.

**Full name of responsible person**

Dr.Akbar Fotoouhi

**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**

Tehran 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, Tehran, Iran.

**Full name of responsible person**

Dr.Sina Safamanesh

**Position**

Laparoscopic Fellowship

**Other areas of specialty/work****Street address**

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

**City**

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**Postal code****Phone**

+98 21 64351

**Fax****Email**

sina\_270@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Minimally Invasive Surgery Research Center.

**Full name of responsible person**

Dr.Abdolreza Pazouki

**Position**

Laparoscopic Fellowship

**Other areas of specialty/work****Street address**

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

**City**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Minimally Invasive Surgery Research Center

**Full name of responsible person**

MOhadeseh pishgah

**Position**

Expert stata

**Other areas of specialty/work****Street address**

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

**City**

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**Postal code****Phone**

+98 21 6655 5447

**Fax****Email**

mo.pishgah@yahoo.com, research@lapsurg.ir

**Web page address**

## 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*