# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 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**

Mnimally 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 epigastricl 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 exesive 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**

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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**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
MOhadeseh pishgah

**Position**
Expert stata

**Other areas of specialty/work**

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**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*