

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### A comparison of results of gallbladder extraction through umbilical port versus subxiphoid port in laparoscopic cholecystectomy: A randomized controlled trial

#### Protocol summary

##### Study aim

Comparison of results of gallbladder extraction through umbilical port versus subxiphoid port in laparoscopic cholecystectomy.

##### Design

Randomized control trial with parallel groups , double blind

##### Settings and conduct

In Shahid Modarres Hospital of Tehran, eligible patients will be assigned in two groups of gallbladder extraction through umbilical and subxiphoid port. All the patients and people in charge of assessment are unaware of gallbladder extraction site during surgery. Pain level will be assessed in all the patients at 3, 12 and 24 hours after surgery using Visual analogue scale (VAS) also days using analgesic drug will be noted. After one month patients will be evaluated for surgery site infection and satisfaction with the surgery in scale of 1 to 10. After one year patients will be evaluated for hernia.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria in considered having at least one of the risk factors for incisional hernia including diabetes, age over 60, BMI over 30 and smoking. Exclusion criteria in this study is open cholecystectomy, gallbladder or intestinal rupture during surgery, previous surgery on midline or upper part of stomach and patient not giving consent.

##### Intervention groups

Patients would be divided in two groups. In one group gallbladder extraction happens through umbilical port and in other group through subxiphoid port.

##### Main outcome variables

Average of pain level ; Days using analgesic drugs after surgery; Patient satisfaction level; Surgery site infection; Incisional hernia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161217031440N2**

Registration date: **2020-03-25, 1399/01/06**

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

Last update: **2020-03-25, 1399/01/06**

Update count: **0**

##### Registration date

2020-03-25, 1399/01/06

##### Registrant information

##### Name

Barmak Gholizadeh

##### Name of organization / entity

Shahid beheshti university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2298 6403

##### Email address

b\_gholizadeh@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-05, 1398/07/13

##### Expected recruitment end date

2020-10-04, 1399/07/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A comparison of results of gallbladder extraction through umbilical port versus subxiphoid port in laparoscopic cholecystectomy: A randomized controlled trial

### Public title

A comparison of results of gallbladder extraction through umbilical port versus subxiphoid port in laparoscopic cholecystectomy: A randomized controlled trial

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Diabetes Age over 60 BMI more than 30 Smoking

#### Exclusion criteria:

open cholecystectomy gallbladder rupture during surgery Intestinal rupture during surgery previous surgery on midline or upper part of stomach patient not giving consent

### Age

No age limit

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Care provider

### Sample size

Target sample size: **294**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Patients eligible for the study based on inclusion criteria, will be randomly assigned into two groups of different gallbladder extraction site using randomized blocks method.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Patients are unaware of gallbladder extraction site through their own surgery. People in charge of the patient assessment are not aware of gallbladder extraction site in each individual patient.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

### Street address

Third Floor, School of Medicine, Aarabi st., Yaman st., Shahid Chamran hwy.

### City

Tehran

### Province

Tehran

### Postal code

193954719

### Approval date

2020-02-23, 1398/12/04

### Ethics committee reference number

IR.SBMU.RETECH.REC.1398.868

## Health conditions studied

### 1

#### Description of health condition studied

Complications after laparoscopic cholecystectomy

#### ICD-10 code

K80

#### ICD-10 code description

Cholelithiasis

## Primary outcomes

### 1

#### Description

Incisional hernia incidence

#### Timepoint

One year after surgery

#### Method of measurement

Asking

## Secondary outcomes

### 1

#### Description

Pain level after surgery

#### Timepoint

3, 12 and 24 hours after surgery

#### Method of measurement

Visual analogue scale

### 2

#### Description

Days using analgesic drugs after surgery

#### Timepoint

One month after surgery

#### Method of measurement

Days using

### 3

#### Description

Surgery site infection incidence

**Timepoint**

One month after surgery

**Method of measurement**

Signs such as inflammation and purulent discharge from incision line

**4**

**Description**

Patients satisfaction with surgery

**Timepoint**

One month after surgery

**Method of measurement**

1 to 10 scale

**Intervention groups**

**1**

**Description**

Intervention group: Extraction of gallbladder through subxiphoid port

**Category**

Prevention

**2**

**Description**

Control group: Extraction of gallbladder through umbilical port

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Modarres medical center

**Full name of responsible person**

Barmak Gholizadeh

**Street address**

Shahid Modarres medical center, Saadat abad st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1998734383

**Phone**

+98 21 2208 3109

**Email**

barmak.gholizadeh@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zargi

**Street address**

3rd Floor, School of Medicine, Arabi st., Yaman st., Shahid Chamran hwy.

**City**

tehran

**Province**

Tehran

**Postal code**

193954719

**Phone**

+98 21 2243 9781

**Email**

Mpajouhesh@sbmu.ac.ir

**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**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Barmak Gholizadeh

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Shahid Modarres hospital, Saadat Abad st.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available