

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.

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1998734383

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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.

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+98 21 2243 9781

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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

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Shahid Modarres hospital, Saadat Abad st.

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Person responsible for scientific inquiries

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Person responsible for updating data

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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