

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The comparison between result of single port laparoscopic cholecystectomy with 4 ports cholecystectomy

Protocol summary

Summary

In this study in the period of time 60 patients (30 patients in each group) who operated with traditional (4 ports) or new (one port) laparoscopic cholecystectomy evaluated about post operative pain and need for analgesic, length of surgery, rate of change to open surgery, rate of gall bladder rupture, intra operative hemorrhage, days of admission, wound infection and conclusions compared in two groups. Inclusion criteria is included: patients with symptomatic cholelithiasis; without complications; between 14 to 70 years old; BMI less than 35; no history of other diseases; no history of previous abdominal surgery. Exclusion criteria is included: patients with complicated cholelithiasis; less than 14 years old; more than 70 years old; BMI more than 35; history of other diseases; history of previous abdominal surgery. In this study primary outcome is post operative pain and other outcomes are secondary outcome. Severity of pain in both groups evaluated by VAS in period of 3, 6, 12, 24 hours and three days after surgery. Volume of bleeding estimated by volume of blood that suctioned during surgery. If no complication not occurred patients followed monthly to two months by phone contact or outpatient visits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105026359N1**
Registration date: **2011-07-18, 1390/04/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-07-18, 1390/04/27

Registrant information

Name

Alireza Barband

Name of organization / entity

Tabriz University Of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 41 1542 2862

Email address

soroushm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences and Health Services

Expected recruitment start date

2011-08-22, 1390/05/31

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between result of single port laparoscopic cholecystectomy with 4 ports cholecystectomy

Public title

The comparison between result of single port laparoscopic cholecystectomy with 4 ports cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients with symptomatic cholelithiasis; without complications; between 14to70 years old; BMI less than 35 ; no history of other diseases ; no history of previous abdominal surgery. Exclusion criteria:: patients with complicated cholelithiasis ;less than 14 years old ,more than 70 years old ; BMI more than 35 ; history of other diseases; history of previous abdominal surgery

Age

From **14 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University Of Medical Sciences and Health Services

Street address

Tabriz University Of Medical Sciences and Health Services , Golgasht Ave, Tabriz

City

Tabriz

Postal code

5166614756

Approval date

2011-04-10, 1390/01/21

Ethics committee reference number

391/5/4

Health conditions studied**1****Description of health condition studied**

Cholelithiasis

ICD-10 code

K80

ICD-10 code description

Cholelithiasis

Primary outcomes**1****Description**

post operative pain

Timepoint

3,6,12,24hours and three days after surgery

Method of measurement

VAS

Secondary outcomes**1****Description**

Length of operation

Timepoint

In the period of operation

Method of measurement

minute

2**Description**

Rate of change to open surgery

Timepoint

In the period of operation

Method of measurement

Number percent

3**Description**

Rate of gall bladder rupture

Timepoint

In the period of operation

Method of measurement

Number percent

4**Description**

Rate of intraoperative bleeding

Timepoint

In the period of operation

Method of measurement

Millilitre(ml)

5**Description**

Length of admission

Timepoint

Admission to Discharge

Method of measurement

Day

6

Description

Rate of wound infection

Timepoint

Until two months after surgery

Method of measurement

Number percent

Intervention groups

1

Description

In the cases laparoscopic cholecystectomy made with only one umbilical port but in control with standard 4 port

Category

Treatment - Surgery

2

Description

In case group laparoscopic cholecystectomy made only by one umbilical port.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Sina Hospital

Full name of responsible person

Dr.Mohammad Soroush

Street address

Sina Hospital , between Montazeri and Hafez, Azadi Ave, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University Of Medical Sciences and Health Services

Full name of responsible person

Miss Maghami

Street address

Tabriz University Of Medical Sciences and Health Services, Golgasht Ave, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University Of Medical Sciences and Health Services

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

Tabriz University Of Medical Sciences and Health Services

Full name of responsible person

Dr.Mohammad Soroush

Position

Rezident Of General Sergury

Other areas of specialty/work

Street address

Tabriz University Of Medical Sciences and Health Services , Golgasht Ave, Tabriz

City

Tabriz

Postal code

5166614756

Phone

+98 41 1335 5921

Fax

+98 413355944

Email

Soroushm@tbzmed.ac.ir

Web page address

www.tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

General Surgery Group Sina Hospital

Full name of responsible person

Dr.Alireza Barband

Position

Associate Professor Of General Surgery

Other areas of specialty/work

Street address

Sina Hospital between Montazeri and Hafez , Azadi Ave, Tabriz

City

Tabriz

Postal code

51636398888

Phone

+98 41 1542 2862

Fax
+98 41 1542 9060
Email
Soroushm@tbzmed.ac.ir
Web page address

+98 41 1335 5921
Fax
+98 41 1335 5944
Email
Soroushm@tbzmed.ac.ir
Web page address
WWW.tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University Of Medical Sciences and Health Services
Full name of responsible person
Dr.Mohammad Soroush
Position
Rezident Of General Sergury
Other areas of specialty/work
Street address
Tabriz University Of Medical Sciences and Health Services, Golgasht Ave, Tabriz
City
Tabriz
Postal code
5166614756
Phone

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