

# 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

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## Person responsible for scientific inquiries

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##### Name of organization / entity

General Surgery Group Sina Hospital

##### Full name of responsible person

Dr.Alireza Barband

##### Position

Associate Professor Of General Surgery

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Sina Hospital between Montazeri and Hafez , Azadi Ave, Tabriz

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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

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**City**

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**Postal code**

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**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*