

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of three port with standard four port laparoscopic cholecystectomy

Protocol summary

Summary

The aim of this study is to compare the cholecystectomy laparoscopic 3 and 4 portes of safety, this study is randomized clinical trial. Participants including major eligibility criteria, one hundred patients choice among sick candidate for cholecystectomy treatment in sina hospital. Patient divide two fifty groups with similar risk factor sub intervention group with three portes and control group with four ports cholecystectomyY laparoscopic. All patients treatment via one surgen and one kind drug anesthesia and opioid with relievable. Main out come measures: Cholecystectomy laparoscopic 3 and 4 portes of safety based on: Bleeding, Kind of sore. Purposes approviated evaluation are checking time of hospital admission and measure of used opioid and sedation and transformation to open cholesistectomy and checking of patientes satisfaction. usage purposeses include painless after surgery and decrease of costes and better resulte of cosmetic.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110219788N1**

Registration date: **2015-06-13, 1394/03/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-13, 1394/03/23

Registrant information

Name

Reza Mirzaie

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41333470549

Email address

mirzaira@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of medical sciences/ Vice chancellor for reseach

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three port with standard four port laparoscopic cholecystectomy

Public title

Comparison of three port with standard four port laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with symptomatic cholelithiasis and acute and chronic cholesistitis;

Exclusion criteria: pregnancy; morbid obesity; common bile duct stones; Obstructive jaundice; cirrhosis; uncorrectable coagolopathy; previous surgery in the upper abdomen; heart failure; ascites .

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz University of Medical Sciences

Street address

Central Building of Tabriz University of Medical Sciences, Golgasht Avenue, azadi street, Tabriz

City

Tabriz

Postal code**Approval date**

2014-12-18, 1393/09/27

Ethics committee reference number

93149

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

Colelithiasis

ICD-10 code

k80.0, K8

ICD-10 code description

Calculus of gallbladder with acute cholecystitis, Calculus of gallbladder with other cholecystitis, Calculus of gallbladder without cholecystitis

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

Content of beelding

Timepoint

Time of operation, After surgery

Method of measurement

Based on: Observation beelding drain discharge

2**Description**

Use narcotic drug

Timepoint

Surgery time and after surgery

Method of measurement

With pac system

3**Description**

Hospitalization time

Timepoint

from entrance unit until discharge

Method of measurement

numeration of hospitalization days

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

Patient satisfaction of pain decline

Timepoint

After surgery

Method of measurement

From pain scale

2**Description**

Damage of bile ducts

Timepoint

In operation time and after

Method of measurement

With observation and written complication

Intervention groups**1****Description**

Intervention:3 ports laparoscopic in patient with gallstone and colisistit

Category

Treatment - Surgery

2**Description**

Control:cholecystectomy laparoscopic 4 ports in patient

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Sina Hospital

Full name of responsible person

Dr Reza Mirzaie

Street address

Sina Hospital, Between Maralan and Hafez, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences/ Vice chancellor
for reseach

Full name of responsible person

Dr Alireza Barband

Street address

Central Building of Tabriz University of Medical
Sciences, Golgasht Avenue, Azadi Street,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/ Vice chancellor for
reseach

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 Science

Full name of responsible person

Dr Reza Mirzaie

Position

Surgent Resident

Other areas of specialty/work

Street address

Sina Hospital, Between Maralan and Hafez Street,
Tabriz

City

Tabriz

Postal code

Phone

+98 41 3329 8511

Fax

Email

remix1360@gmail.com mirzaira@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Dr Alireza Barband

Position

Professor Assistant

Other areas of specialty/work

Street address

Central Building of Tabriz University of Medical
Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3335 5924

Fax

Email

alibarband@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University Of Medical Science

Full name of responsible person

Dr Reza Mirzaie

Position

Surgent Resident

Other areas of specialty/work

Street address

Sina Hospital, Between Maralan and Hafez Street,
Tabriz

City

Tabriz

Postal code

Phone

+98 41 3541 2101

Fax

Email

remix1360@gmail.com mirzaira@tbzmed.ac.ir

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