Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 sicks 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 cholecystectomY 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 purpoeses 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
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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
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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
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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
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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