Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison between the result of laparoscopic versus Needlescopic cholecystectomy as the surgical treatment of chronic cholecystitis

Protocol summary

Summary

This randomized double blind clinical trial is to evaluate the results of Laparoscopic versus Needlescopic cholecystectomy in patients with chronic cholecystitis. A total of 70 patients will be randomly assigned into two thirty five persons groups; For the first group Laparoscopic cholecystectomy and for another one Needlescopic cholecystectomy will be done and the two groups will be compared in terms of the time of surgery, volume of intra-operation bleeding, post operative pain (with visual analog scale) and IV opium drug consumption by a person who are not aware of the intervention received.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105216542N1**
Registration date: **2011-07-23, 1390/05/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-23, 1390/05/01

Registrant information

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Name of organization / entity
Ahwaz Jundishapour University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Jundishapour University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the result of laparoscopic versus Needlescopic cholecystectomy as the surgical treatment of chronic cholecystitis

Public title

A comparison between the result of laparoscopic versus Needlescopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Suffering from gall stone, candidate for laparoscopic cholecystectomy, willing to participate
Exclusion criteria: Having history of coagulation disorder, having icter or history of Pancreatitis, history of surgery on upper abdomen

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Jundishapour University of Medical Sciences

Street address
Golestan Boulevard, Ahvaz

City
Ahvaz

Postal code

Approval date
2010-10-10, 1389/07/18

Ethics committee reference number
2902

Health conditions studied

1

Description of health condition studied
Choronic Cholecystitis

ICD-10 code
K80.1

ICD-10 code description
Calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description
Pain after surgery

Timepoint
2 hours after surgery, 6 hours after surgery,24 hours after surgery

Method of measurement
Visual Analoge scale

Secondary outcomes

1

Description
Time of surgery

Timepoint
Time from beginning surgery to end of surgery

Method of measurement
minute

Intervention groups

1

Description
Intervention group: Needlescopic Cholecystectomy

Category
Treatment - Surgery

2

Description
Control group: Laparascopic Cholecystectomy

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Razi Hospital

Full name of responsible person
Saeed Goudarzi

Street address
Golestan Boulevard, Ahvaz

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jundishapour University of Medical Sciences

Full name of responsible person
Dr. Mostafa Feghhi, Vice-Chancellor for Research

Street address
Vice-Chancellor For Research, Ahvaz Jundishapour University Of Medical Sciences

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Ahvaz

Grant name

Grant code / Reference number

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

Title of funding source
Jundishapour University of Medical Sciences

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

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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