

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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

###### Name

Saeed Goudarzi

###### Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1333 3050

###### Email address

goudarzi.s@ajums.ac.ir

##### 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

Chronic 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 Analogue 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: Laparoscopic 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 Fegghi, Vice-Chancellor for Research  
**Street address**  
Vice-Chancellor For Research, Ahvaz Jundishapour University Of Medical Sciences  
**City**  
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*

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**Web page address**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Ahvaz Jundishapour University of Medical Sciences  
**Full name of responsible person**  
Dr. Saeed Goudarzi  
**Position**  
General Surgery Resident  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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Dr Mehdi Asgari  
**Position**  
Assistant Professor Of General Surgery  
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**City**

## Person responsible for updating data

### Contact

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Ahvaz Jundishapour University of Medical Sciences  
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Dr Saeed Goudarzi  
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General surgery Resident  
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**Phone**  
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**Email**  
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**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*