

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Laparoscopic versus open appendectomy: compare outcomes and complications in the treatment of complicated appendicitis

Protocol summary

Summary

Purpose: To evaluate laparoscopic appendectomy during complicated acute appendicitis treatment **Method:** In this study, all patients suspected of having complicated acute appendicitis undergo further investigation. Once the diagnosis is established, two types of surgery are explained for the patients (Open and Laparoscopic). After taking the informed consent, the patients enter the study voluntarily and are randomly assigned in Open and Laparoscopic Groups. A team of surgeons and senior assistants working in Sina Hospital performs the surgery. Minimum number of 48 patients undergoes the surgery in each group. **Interventions:** Open Appendectomy is performed for the patients in the control group and Laparoscopic Appendectomy in the experiment group. **Inclusion Criteria:** Patients suspected of having complicated acute appendicitis except for the definite cases of abscesses and phlegmon. **Exclusion Criteria:** History of abdominal or pelvic surgery, patients who are not diagnosed with complicated acute appendicitis during the operation by surgeon or pathologist after the surgery, diagnosis of abscesses and phlegmon, and pregnant mothers. **Consequences:** Primary Outcome: Comparing the length of surgery; Secondary Outcome: Surgical site infection, intra-abdominal abscess, post-operative pain, complications such as nosocomial infections, incisional hernia, etc., length of stay, and the need for reoperation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102724747N1**

Registration date: **2017-06-06, 1396/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-06, 1396/03/16

Registrant information

Name

Amir Mangouri Miandoab

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3330 8229

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mangouria@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Laparoscopic versus open appendectomy: compare outcomes and complications in the treatment of complicated appendicitis

Public title

Laparoscopic versus open appendectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients suspected of having complicated acute appendicitis
Exclusion criteria: History of abdominal or pelvic surgery; people who have been diagnosed abscess or phlegmon

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 96

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Golgasht avenue, Tabriz University of Medical Sciences

City

Tabriz

Postal code

5165665931

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

IR.TBZMED.REC.1395.1027

Health conditions studied

1

Description of health condition studied

Acute Appendicitis

ICD-10 code

k35

ICD-10 code description

Acute appendicitis

Primary outcomes

1

Description

Duration of surgery

Timepoint

During surgical intervention

Method of measurement

Timer

Secondary outcomes

1

Description

Surgical site infection

Timepoint

During hospitalization, one month after discharge

Method of measurement

Follow up

2

Description

Intra-abdominal abscess

Timepoint

During hospitalization, one month after discharge

Method of measurement

Follow up

3

Description

Pain After Surgery

Timepoint

During hospitalization

Method of measurement

Follow up

4

Description

Complications such as nosocomial infections, hernia incisional and ...

Timepoint

During hospitalization, one month after discharge

Method of measurement

Follow up

5

Description

Length of hospitalization after surgery

Timepoint

During hospitalization

Method of measurement

Timer

6

Description

The need for further surgery

Timepoint

During hospitalization, one month after discharge

Method of measurement

Follow up

Intervention groups

1

Description

Control Group: Open Appendectomy

Category

Treatment - Surgery

2

Description

Intervention Group: Laparoscopic Appendectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Vahideh Nemati

Street address

Azadi Ave, Hafez Square

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Akram Azari

Street address

3rd Floor, Faculty of Medicine, opposite the headquarters of the University, University Avenue

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz 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

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Amir Mangouri

Position

Resident of General Surgery

Other areas of specialty/work

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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