Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Laparoscopic Appendectomy Vs Open Appendectomy concerning Early Surgical Site Infection Incidence, Single-Blinded Parallel-Group, Randomized Controlled Trial

Protocol summary

Study aim

To determine and compare early surgical site infection (SSI), intra-abdominal abscess rate, net cost, and postoperative quality of life between open and laparoscopic appendectomy.

Design

Randomized, parallel group, single-blind (data analyst), phase 3 clinical trial in 2025 across all hospitals in Kerman; 162 patients, simple randomization using A/B card draw.

Settings and conduct

The trial will be conducted in 2025 across all hospitals in Kerman. Patients (Alvarado score >5) will be randomized into two groups. Only the data analyst will be blinded. Consent obtained, confidentiality maintained.

Participants/Inclusion and exclusion criteria

Patients aged 15–60 with uncomplicated acute appendicitis, no systemic disease or coagulation disorder, and signed informed consent will be included.

Intervention groups

Both groups undergo appendectomy under general anesthesia by a unified surgical team. Group 1: Open surgery; Group 2: Three-port laparoscopic surgery. Closure and protocols are standardized.

Main outcome variables

Patients will be assessed on days 1, 2, 3, 7, and 14 after surgery for the occurrence of surgical site infection (SSI). The evaluated signs include redness at the incision site; purulent discharge; pain and swelling; fever; and culture results of the discharge in suspected cases. Additionally, the formation of intra-abdominal abscess will be evaluated using abdominal ultrasound. Other variables to be assessed include duration of surgery (minutes); length of hospital stay (days); consumption of opioid analgesics after surgery; and quality of life assessment during the first week post-surgery using the standardized WHO-QOL-BREF questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250507065635N1**
Registration date: **2025-10-01, 1404/07/09**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-01, 1404/07/09**
Update count: **0**

Registration date

2025-10-01, 1404/07/09

Registrant information

Name

Fatemeh Doost Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Laparoscopic Appendectomy Vs Open Appendectomy concerning Early Surgical Site Infection Incidence, Single-Blinded Parallel-Group, Randomized Controlled Trial

Public title
Laparoscopic vs. Open Appendectomy: Surgical Site Infection Study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with acute appendicitis and an Alvarado score greater than five will be included in the study.

Exclusion criteria:

Age
From **10 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **162**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to either open or laparoscopic surgery using simple randomization. To this end, cards containing the letters A or B will be placed in identical envelopes, and one card will be randomly selected for each participant. If the letter A is drawn, the participant will be assigned to the open appendectomy group, and the next participant will be assigned to the laparoscopic appendectomy group. If the letter B is drawn, the participant will be assigned to the laparoscopic appendectomy group, and the next participant will be assigned to the open appendectomy group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients will be blinded to the type of surgery (open/laparoscopic) only before the procedure, and blinding will not be possible after surgery. The surgeon cannot be blinded to the type of surgery. The individual analyzing the results will be blinded to patient allocation, and each surgical method will be assigned codes A and B for data analysis. Therefore, this study will be conducted as a single-blind trial (blinding only for the data analyst).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Afzalipour Hospital-Kerman University of Medical Sciences

Street address
Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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kerman

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Kerman

Postal code
7616913555

Approval date
2025-09-27, 1404/07/05

Ethics committee reference number
IR.KMU.AH.REC.1404.134

Health conditions studied

1

Description of health condition studied
Acute appendicitis

ICD-10 code
K35.80

ICD-10 code description
Unspecified acute appendicitis

Primary outcomes

1

Description
Surgical site infection (SSI). Postoperative days 1, 2, 3, 4, 7, and 14 will be considered as the primary time points for outcome assessment. At these intervals, the surgical wound will be evaluated in terms of its appearance (e.g., potential discharge), blood tests (e.g., leukocyte count), and the presence of intra-abdominal abscesses using ultrasound imaging.

Timepoint
Surgical site infection (SSI). Postoperative days 1, 2, 3, 4, 7, and 14 will be considered as the primary time points for outcome assessment.

Method of measurement
The surgical wound will be evaluated in terms of its appearance (e.g., potential discharge), blood tests (e.g., leukocyte count), and the presence of intra-abdominal abscesses using ultrasound imaging.

Secondary outcomes

1

Description
surgery duration
Timepoint
By a digital clock by minute, and then entering it into a checklist
Method of measurement
Once during an appendectomy for each person

2

Description
Postoperative pain score
Timepoint
For each person, 6, 2, 12, and 24 hours after the operation
Method of measurement
Visual Analog Scale

3

Description
Frequency of use of housing until 48 hours after the operation
Timepoint
until 48 hours after the operation
Method of measurement
Using the patient record

4

Description
Start consuming food
Timepoint
Recording the time of first intake of oral fluids, recording the time of starting a soft diet or light solid food, and recording the time of complete return to a normal diet after surgery
Method of measurement
Recording the time of first intake of oral fluids, recording the time of starting a soft diet or light solid food, and recording the time of complete return to a normal diet after surgery

5

Description
Improve bowel movement
Timepoint
Recording the time of the first gas, recording the time of the first bowel movement, recording the time of hearing bowel sounds, and recording the time of food tolerance without nausea/vomiting
Method of measurement
Recording the time of the first gas, recording the time of the first bowel movement, recording the time of hearing bowel sounds, and recording the time of food tolerance without nausea/vomiting

6

Description
Recovery of physical activity
Timepoint
Record the time when you do not need help to walk or go to the bathroom
Method of measurement
Record the time when you do not need help to walk or go to the bathroom

7

Description
Length of hospital stay after surgery
Timepoint
Length of hospital stay after surgery
Method of measurement
Length of hospital stay by day and then recorded in the checklist

8

Description
Changes in white blood cells and CRP levels after surgery
Timepoint
Twice: once 24 hours after surgery and once 5 days after surgery
Method of measurement
White blood cell count and C-reactive protein level

9

Description
Postoperative quality of life
Timepoint
7 days after surgery
Method of measurement
WHO-QOL-BREF standard questionnaire

Intervention groups

1

Description
Control group: Open appendectomy (OA) performed under general anesthesia through a right lower quadrant abdominal incision using the standard open surgical technique. Skin closure is performed with appropriate sutures following routine protocols. Intervention group: Laparoscopic appendectomy (LA) performed under general anesthesia using a standard three-port laparoscopic technique for appendix dissection and removal. Skin closure is similarly done with sutures according to standard procedures. Both groups' surgeries are conducted by the same surgical team following a unified protocol to minimize bias.
Category
Treatment - Surgery

2

Description
Intervention group: Laparoscopic appendectomy performed under general anesthesia using a standard three-port laparoscopic technique for appendix dissection and removal. The procedure follows

established surgical guidelines and is conducted by a unified surgical team to minimize bias. Skin closure is done with appropriate sutures according to standard practice.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar Hospital, Surgery Department
Full name of responsible person
Dr. Saheb Bahreh Bar
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Recruitment center
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Recruitment center
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Professor . Hamid Sharifi
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Kerman University of Medical Sciences Vice Chancellor for Research and Technology Kerman, Iran
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research@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Doost Mohammadi

Position

staff

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

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Position

reseacher staff

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for updating data

Contact

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Research staff

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Please provide the specific title of the documents or data files to be shared and additional details about them. For example, if individual participant data (IPD) are to be shared, clarify whether all deidentified data will be shared or only a subset, such as data related to the primary outcome.

When the data will become available and for how

long

Please provide information regarding the timing of the release of these documents/data files. Your description should include both the time frame and the start date of access. This can be a specific date, for example, “access will start from January 2020,” or relative timing such as “access will begin 6 months after publication of results.”

To whom data/document is available

Please specify who will be allowed to request access to the data or other study documents. For example, will your data only be available to researchers affiliated with academic institutions, or can industry professionals also apply to receive it?

Under which criteria data/document could be used

Please specify, besides the criteria for who can request the data or documents, any other conditions for using the shared data or documents. For example, what types of analyses are permitted, what kinds of use are allowed, and what mechanisms govern this access? Please list the necessary conditions for submitting requests to access the data or documents.

From where data/document is obtainable

Please guide applicants on where to apply to obtain the desired documents or data files. Applicants should know whom or where to contact to receive the requested materials. Please state preferred communication methods and provide clear contact information such as postal or email addresses, website URLs, telephone and fax numbers, as well as names and addresses of contact persons.

What processes are involved for a request to access data/document

Please provide details about the procedures that the requester must follow to obtain these documents or data files. Your description should be clear enough for the applicant to estimate how long it will take to receive the requested materials after applying.

Comments

Please provide any additional information or comments here if necessary.