Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of short-term outcomes of abdominal wall repair in patients appendectomy with and without peritoneal repair

Protocol summary

Study aim
Comparison of short-term outcomes of abdominal wall repair in appendectomy patients, with and without peritoneal repair

Design
A randomized clinical trial with a control group, with parallel groups, double-blind, will be done on 150 patients aged 4 to 18 years, who were diagnosed with acute appendicitis and underwent emergency appendectomy surgery in Madani Hospital in Karaj. Randomization will be done using permuted balance block randomization technique using STATA software.

Settings and conduct
Generally, appendectomy can be done by open or laparoscopic method. Usually, during laparoscopic appendectomy, peritoneum closure is not one of the preferred practices, but in open appendectomy, some surgeons pay special attention to closing the peritoneum. So far, many studies have investigated whether or not to close the peritoneum on postoperative outcomes. This clinical trial is conducted in Karaj Civil Hospital. In this study, randomization is done by permuted balance block randomization technique. In this double-blind study, patients will be unconscious during the surgery and will not be aware of the wound closure method. The research team will not be aware of the intervention performed on the patients. Patient information and surgical complications will be followed up to one month after the operation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 4 to 18 years with a diagnosis of acute appendicitis Exclusion criteria: presence of abdominal abscess, presence of purulent fluid during surgery, pregnancy, history of malignancy, chronic liver disease, chronic kidney failure, diabetes and psychiatric disorders.

Intervention groups
Appendectomy patients with and without peritoneal repair

Main outcome variables
The primary outcome includes pain and the secondary outcome includes surgical complications such as rupture, infection, bowel obstruction, and mortality.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230207057346N1**
Registration date: **2023-02-14, 1401/11/25**
Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**
Update count: **0**

Registration date
2023-02-14, 1401/11/25

Registrant information
Name
Saeed Habibi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-02-28, 1401/12/09
Expected recruitment end date
2023-05-20, 1402/02/30
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of short-term outcomes of abdominal wall repair in patients appendectomy with and without peritoneal repair

Public title
Comparison of short-term outcomes of abdominal wall repair in appendectomy patients, with and without peritoneal repair
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 4 to 18 years old With the diagnosis of acute appendicitis (confirmed by abdominal ultrasound or CT scan), they undergo emergency appendectomy surgery in Madani Hospital in Karaj.
Exclusion criteria:
Abdominal abscess in preoperative imaging pregnancy The presence of local or disseminated purulent fluid during the operation Chronic liver disease Chronic renal failure Having diabetes mellitus History of malignancy History of psychiatric disorders
Age
From **4 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **151**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients will be randomly assigned using the permuted balance block randomization technique. Blocks of four will be used in this study. Using STATA software, a chain of random numbers from 1 to 6 will be generated to reach the desired sample size. If the generated number is greater than 6, the next number will be generated regardless. The preparation of random allocation sequences of intervention and control groups and placing them in sealed envelopes and numbering with a 5-digit serial number, will be done by a third person, who is not involved in the design of the study. All envelopes have a number. There will be a 5-digit series that will be opened immediately after the patient entrance to the operation room, and the patients will be divided into two intervention and control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the patients will be under anesthesia, during the surgery and will not be informed about how the wound is closed. The research team (interviewers) will not know which intervention was performed on which person.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Alborz University of Medical Sciences, Administrative Town, North Taleghani Blvd., Taleghani Square, Karaj
City
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Alborz
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3149779453
Approval date
2022-10-21, 1401/07/29
Ethics committee reference number
IR.ABZUMS.REC.1401.196

Health conditions studied

1

Description of health condition studied
Unspecified appendicitis
ICD-10 code
K37
ICD-10 code description
Unspecified appendicitis

2

Description of health condition studied
Acute appendicitis
ICD-10 code
K35
ICD-10 code description
Acute appendicitis

3

Description of health condition studied
Other appendicitis
ICD-10 code
K36

ICD-10 code description
Other appendicitis

Primary outcomes

1

Description
Pain
Timepoint
The day after the operation, one week and one month after the operation
Method of measurement
Visual Analogue Scale (VAS) of pain

Secondary outcomes

1

Description
Postoperative complications
Timepoint
Up to one month after surgery
Method of measurement
Physical examination, if needed, conducting tests and questioning the patient, recording in the checklist

Intervention groups

1

Description
Intervention group:
Category
Treatment - Surgery

2

Description
Control group:
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani Hospital of Karaj
Full name of responsible person
Saeed Habibi
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Sponsors / Funding sources

1

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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
Karaj 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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