

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4416 1089

##### Email address

saeedhabibi42@yahoo.com

##### 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**

Karaj

**Province**

Alborz

**Postal code**

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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Alborz University of Medical Sciences, Administrative Town, North Taleghani Blvd., Taleghani Square, Karaj

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Karaj University of Medical Sciences

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Saeed Habibi

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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

##### Name of organization / entity

Karaj University of Medical Sciences

##### Full name of responsible person

Mohammad mahdi Khazravi

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

General Surgery

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## Person responsible for scientific inquiries

### Contact

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Consultant  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

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Saeed Habibi  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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a.karimi1367@gmail.com

## 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