

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Surgical outcome of scalpel versus Diathermy skin lesion in uncomplicated appendectomy

Protocol summary

Study aim

Surgical outcome of scalpel versus Diathermy skin lesion in uncomplicated appendectomy

Design

The study will be double blind and clinical trial. 72 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

Settings and conduct

Patients candidate for uncomplicated appendectomy surgery in Valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20 to 50 years, lack of underlying diseases, patients in need of appendicitis surgery, absence of previous abdominal surgery, do not use corticosteroids and immunosuppressive drugs. Exclusion criteria: Gangrenous appendicitis, abscess appendicitis, cardiac-respiratory arrest during surgery, wound infection during surgery

Intervention groups

In the first group, the skin is cut from the skin to the fascia with a cutter with a cutting mode, and in the second group, the skin is cut from the skin to the fascia using a scalpel.

Main outcome variables

Infection, hematoma, pain, scar scar examination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N175**

Registration date: **2022-05-09, 1401/02/19**

Registration timing: **prospective**

Last update: **2022-05-09, 1401/02/19**

Update count: **0**

Registration date

2022-05-09, 1401/02/19

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-10, 1401/02/20

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Surgical outcome of scalpel versus Diathermy skin lesion in uncomplicated appendectomy

Public title

Surgical outcome of scalpel versus Diathermy skin lesion in uncomplicated appendectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20 to 50 years Lack of underlying diseases Patients in need of appendicitis surgery Absence of previous abdominal surgery Do not use corticosteroids and immunosuppressive drugs

Exclusion criteria:

Gangrenous appendicitis Abscess appendicitis Cardiac-respiratory arrest during surgery Wound infection during surgery

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. The analysis is done by the analyst and outcome evaluator (two-blind) and the participant. Analysts, evaluators and participants are not aware of the consequences of grouping. The specialist assistant is unaware of the type of operation in each group and the surgeon is aware of the type of operation and patients are not aware of their group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam

complex, Basij square ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2022-03-13, 1400/12/22

Ethics committee reference number

IR.ARAKMU.REC.1400.360

Health conditions studied**1****Description of health condition studied**

uncomplicated appendectomy

ICD-10 code

K35.8

ICD-10 code description

Other and unspecified acute appendicitis

Primary outcomes**1****Description**

Infection

Timepoint

After surgery

Method of measurement

Physical examination

2**Description**

Hematoma

Timepoint

After surgery

Method of measurement

Physical examination

3**Description**

Pain

Timepoint

After surgery

Method of measurement

Physical examination

4**Description**

Examination of wound scars

Timepoint

After surgery

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: the skin is cut from the skin to the fascia with a cutter with a cutting mode

Category

Treatment - Surgery

2

Description

Intervention group2: the skin is cut from the skin to the fascia using a scalpel.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Siamak Rakei

Street address

Valiasr square, Valiasr hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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resident of surgery

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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