

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### 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

##### City

Arak

##### Province

Markazi

##### Postal code

848176941

##### Phone

+98 86 3222 2003

##### Email

s.rakei@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Alireza Kamali

##### Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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##### Province

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##### Postal code

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##### Email

alikalaliir@yahoo.com

#### 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

##### Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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##### Province

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3814957558

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##### Email

alikalaliir@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Siamak Rakei

##### Position

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ameneh Nemati

**Position**

resident of surgery

**Latest degree**

Specialist

**Other areas of specialty/work**

General Practitioner

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a\_nemati87@yahoo.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