Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Surgical outcome of scalpel verus Diathermy skin lesion in uncomplicated appendectomy

Protocol summary

Study aim
Surgical outcome of scalpel verus 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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Iran (Islamic Republic of)

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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 verus Diathermy skin lesion in uncomplicated appendectomy

Public title
Surgical outcome of scalpel verus 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 comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak
City
Arak
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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
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Sponsors / Funding sources

1

Sponsor
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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
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Full name of responsible person
Dr Alireza Kamali
Position
Associate professor
Latest degree
Specialist
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Person responsible for updating data

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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