Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of appendectomy wound healing by semi-plastic and subcuticular methods.

Protocol summary

Study aim
Comparison of appendectomy wound repair with two semi-plastic subcuticular methods.

Design
The study is a clinical trial with parallel groups, triple blind, randomized, on 80 patients. For randomization, the random block method (balance block randomization) is used.

Settings and conduct
This study is conducted on uncomplicated appendicitis patients of Besat Hospital, Hamedan. In this study, after meeting the entry and exit criteria, the patients will be randomly divided into two intervention groups of 40 people, first and second. In the first intervention group, appendectomy wound closure will be performed using semi-plastic suture, and in the second intervention group, it will be performed using subcuticular suture. In this study, patients and researchers and statistical analysts will be unaware of the study and details.

Participants/Inclusion and exclusion criteria
Patients with uncomplicated appendicitis with informed consent in the age range of 15-65 years were included in the study, but patients with underlying problems, smoking and antibiotic use, history of abdominal surgery and obesity will be excluded from the study.

Intervention groups
First group: appendectomy wound closure is done using semi-plastic method. Second group: appendectomy wound closure is done using subcuticular method.

Main outcome variables
The color of wound secretions; the smell of wound secretionsl the color of tissues around the wound; the condition of the wound in terms of granulation and epithelization; the width of the scar; the warmth of the wound; the opening of the wound; pain.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220821055766N1**
Registration date: **2022-08-31, 1401/06/09**
Registration timing: **prospective**

Last update: **2022-08-31, 1401/06/09**
Update count: **0**

Registration date
2022-08-31, 1401/06/09

Registrant information

Name
Sara Banoeizadeh
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
2022-09-23, 1401/07/01

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of appendectomy wound healing by semi-plastic and subcuticular methods.

Public title
Comparative study of appendectomy wound healing by semi-plastic and subcuticular methods.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Appendicitis is uncomplicated The age range is 15-65 years old Willingness to attend the study
Exclusion criteria:
Patients with subcutaneous fat greater than 4 cm Patients with underlying diseases Patients for whom a drain is placed at the surgical site according to the surgeon's order Patients who have received any type of antibiotic in the last 48 hours Patients who have a history of abdominal surgery Patients with acquired or congenital immunodeficiency Patients who smoke Patients taking immunosuppressive drugs Patients who, for any reason, cannot come for follow-up
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
We will use the quadruple block randomization method. For this purpose, we prepare four sheets of paper. On two sheets we write the letter S meaning "semi-plastic" and on the other two sheets we write the letter C meaning "subcuticular". The sheets are mixed together and with the reference of each eligible patient, one of the sheets will be drawn randomly and based on this drawn sheet, whether it is S or C, they will be assigned to one of the two intervention groups. After all four sheets are randomly drawn, the above procedure will be continued for the next four patients until the desired sample size (80 patients) is reached.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the participants and patients are aware of the general process of the research, but they are unaware of the division into intervention groups in randomization. Also, the person responsible for data collection and the person responsible for data analysis are also unaware.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Hamedan University of Medical Sciences, Shahid Fahmideh St.
City
Hamadan
Province
Hamadan
Postal code
65178
Approval date
2022-08-22, 1401/05/31
Ethics committee reference number
IR.UMSHA.REC.1401.462

Health conditions studied

1

Description of health condition studied
Appendicitis
ICD-10 code
K38.8
ICD-10 code description
Other specified diseases of appendix

Primary outcomes

1

Description
The amount of wound secretions in two Semi-plastic Subcuticular suture methods will be compared.
Timepoint
Second day, tenth day, one month after surgery
Method of measurement
Wound healing checklist.

2

Description
The color of wound secretions will be compared in two Semi-plastic Subcuticular suture methods.
Timepoint
Second day, tenth day, one month after surgery
Method of measurement
Wound healing checklist.

3

Description

Wound odor in two Semi-plastic Subcuticular suture methods will be compared.

Timepoint

Second day, tenth day, one month after surgery

Method of measurement

Wound healing checklist

4

Description

The color of the tissues around the wound will be compared in two methods of Semi-plastic and Subcuticular suture.

Timepoint

Second day, tenth day, one month after surgery

Method of measurement

Wound healing checklist

5

Description

The condition of the wound in terms of granulation and epithelization will be compared in two methods of Semi-plastic and Subcuticular suture.

Timepoint

Second day, tenth day, one month after surgery

Method of measurement

Wound healing checklist

6

Description

The amount of pain in two Semi-plastic Subcuticular suture methods will be compared.

Timepoint

Second day 36 hours after surgery, tenth day, one month after surgery

Method of measurement

Visual pain scale and VAS

7

Description

The condition of the wound in terms of opening will be compared in two methods of Semi-plastic and Subcuticular suture.

Timepoint

Second day, tenth, one month after surgery

Method of measurement

Wound healing checklist

8

Description

The condition of the wound in terms of heat will be compared in two methods of Semi-plastic and Subcuticular sutures.

Timepoint

Second day, tenth day, one month after surgery

Method of measurement

Wound healing checklist

9

Description

The condition of the wound in terms of scar width will be compared in two methods of Semi-plastic and Subcuticular suture.

Timepoint

Second day, tenth day, one month after surgery

Method of measurement

Wound healing checklist

Secondary outcomes

1

Description

Body imaging

Timepoint

Second day, tenth day, one month after surgery

Method of measurement

Littleton et al.'s Body Image Fear Questionnaire (BICI)

Intervention groups

1

Description

The first intervention group: closing the wound with a semi-plastic suture. The method of conducting the study will be that after randomization, the patients, if placed in this group, will undergo surgery by a surgeon and scrub with a similar method. After appendectomy and after ensuring hemostasis, the layers of peritoneum, muscles and fascia will be sewn separately and then according to the placement of patients in this intervention group, they will be sutured in the relevant skin area, which will be sutured using Nylon thread (Kat, No. 3-0, Supa Co., Iran) will be used by the surgeon in a semi-plastic way.

Category

Prevention

2

Description

The second intervention group: closing the wound with subcuticular suture. The method of conducting the study will be that after randomization, if the patients are placed in this group, they will undergo surgery by a surgeon and scrub with a similar method. After appendectomy and after ensuring hemostasis, the layers of the peritoneum, muscles and fascia will be sewn separately, and then according to the placement of the patients in this intervention group, they will be sutured in the relevant skin area, which will be sutured using nylon thread. (Cut, No. 3-0, Supa Company, Iran) will be performed subcuticular by the surgeon.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital

Full name of responsible person
Dr. Rasool Salimi

Street address
Besat Specialist and Subspecialty Hospital, Shahid Beheshti Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Sara banoeizadeh

Position
Master's student in the operating room

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All individual data is shared after de-identifying individuals, including: data on pain and wound healing.
When the data will become available and for how long
The data will be shared three months after the results are published.
To whom data/document is available
All researchers can take action to receive data.
Under which criteria data/document could be used
The data is provided on the condition that, firstly, it has a clear purpose for using the data; secondly, if this data is used; The primary source of data should be mentioned.
From where data/document is obtainable
To receive data, you can refer to the following email address: sara.banoei@gmail.com
What processes are involved for a request to access data/document
After sending the request to the email address, the data will be sent as soon as possible.
Comments