

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of Subcuticular and Semi-mattress Suture Size and Complications in Appendectomy Surgical Scar

Protocol summary

Study aim

The current study aimed to compare subcuticular and semi-mattress appendectomy wound suturing methods in terms of pain, wound complications, scar width and patients' satisfaction to introduce a more suitable method.

Design

Randomized clinical trial with parallel groups without blinding which will be conducted on 50 patients undergoing appendectomy.

Settings and conduct

This parallel RCT (phase III) study will be conducted at Imam Sajjad Hospital of Ramsar from September 2019 to March 2020. 50 patients in two groups of 25 will be enrolled. Included patients are diagnosed with acute appendicitis by a surgeon and treated with open appendectomy. Patients will be assigned into two groups; intervention group A undergoing subcuticular suture and intervention group B undergoing semi-mattress suture. Patients are randomized in block of 5 patients. Follow-up will take place on 3rd, 7th and 30 days after surgery by a surgeon. Patients will be evaluated for pain severity, and aesthetic outcome by Visual Analog Scale (VAS). Surgical site infection, scar width and other complications will be evaluated by direct observation. Subsequently groups will be compared with each other. With respect to nature of the study blinding is not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Acute uncomplicated appendicitis, Informed consent Exclusion criteria: Immunodeficiency, Age > 18 years and BMI < 30 kg/m²

Intervention groups

Each group receives different suturing technique for their surgical wound. One group is treated with non-absorbable subcuticular sutures and other group will receive semi-mattress sutures

Main outcome variables

Width of surgical scar a month after appendectomy;

Aesthetic VAS score one month after surgical intervention; Prevalence of surgical site and suturing complications on 3rd, 7th and 30 days after appendectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190813044523N1**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Mohammad Hadizadeh Neisanghalb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5522 2031

Email address

h.of.mohammad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Subcuticular and Semi-matress Suture Size and Complications in Appendectomy Surgical Scar

Public title

Comparison of Two Suturing Methods in Appendectomy Repairs

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Uncomplicated acute appendicitis Informed consent

Exclusion criteria:

Immunodeficiency BMI<30 kg/m2

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of 5 Considering the sample size of 50, 10 blocks with 20 cards (10 cards for each group) will be selected; by selecting each block, 5 patients will be assigned into each group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical committee of Ramsar Campus- Mazandaran University of Medical Sciences

Street address

Taleghani St, Taleghani 20 Alley

City

Ramsar

Province

Mazandaran

Postal code

4691786953

Approval date

2019-05-20, 1398/02/30

Ethics committee reference number

IR.MAZUMS.RIB.REC.1398.004

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

Acute appendicitis

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

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

Width of scar

Timepoint

One month after surgical intervention

Method of measurement

Ruler

2**Description**

Aesthetic of surgical scar

Timepoint

One month after surgical intervention

Method of measurement

VAS (visual analog scale)

3**Description**

Wound dehiscence

Timepoint

3rd, 7th and month after surgical intervention

Method of measurement

Physical examination by physician

4**Description**

Pain at surgical site

Timepoint

3rd and 7th day after surgical intervention

Method of measurement

VAS (visual analog scale)

5**Description**

Wound infection

Timepoint

3rd and 7th day after surgical intervention

Method of measurement

Physical examination by physician

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A (Subcuticular suture): In this group of patients, after appendectomy, the subcutaneous tissue is repaired with absorbable stitches and then, the skin is going to be sutured subcutaneously with 3-0 nylon stitches. In subcuticular suturing method, needle is introduced in beginning of the wound then its run through subcuticular layer of skin. In the end needle exits through the end of the wound.

Category

Treatment - Surgery

2

Description

Intervention group B (Semi-mattress suture): In this group of patients, after appendectomy, subcutaneous tissue is repaired with absorbable stitches and then, the skin is sutured with semi-mattress technique with 3-0 nylon stitches. Semi-mattress suturing method is a variant of Vertical mattress sutures, In Semi-mattress method, needle is introduced through edge of the wound then it is run through subdermal layers and after passing through subcuticular layer of the opposite edge, needle exits on the same side of introduction. each suture is done separately.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Hospital of Ramsar

Full name of responsible person

Mohammad Hadizadeh Neisanghalb

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Enghelab sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ramsar Campus - Mazandaran University of Medical Sciences

Full name of responsible person

Davood Farzin

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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

Ramsar Campus - Mazandaran 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

Ramsar Campus - Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Hadizadeh Neisanghalb

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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 collected deidentified data for primary and secondary outcome measures are going to be shared

When the data will become available and for how long

after publishing the study, data are going to be available

To whom data/document is available

data are going to be available to all researchers and clinician irrespective to their employment sector

Under which criteria data/document could be used

permission are granted upon request for secondary and meta-analysis

From where data/document is obtainable

requests are gathered through principle researcher's e-mail address

What processes are involved for a request to access data/document

upon verification of request and reason data are given in three month.

Comments