

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Subcuticular and Transdermal Appendectomy Repairs in appendectomy patients; a Randomized Clinical Trial

Protocol summary

Study aim

The current study aimed to comparing subcuticular and transdermal appendectomy wound stitching methods in terms of pain, infection rate, and patients' satisfaction to introduce the more suitable method.

Design

Patients randomly assigned into two groups of randomized clinical trials with a parallel design and 1:1 ratio. The sample size was 210 subjects based on previous studies. The subjects were studied and followed up in two groups of 105 patients; the first group as the subcuticular method and the second group as the transdermal method.

Settings and conduct

In Shahid Modarres Hospital of Tehran, after obtaining informed consent, patients underwent the appendectomy and then the incision line was stitched using subcuticular and transdermal method in two groups. Then they were examined and compared.

Participants/Inclusion and exclusion criteria

The inclusion criteria were the patients with appendicitis symptoms referred to the Emergency Department of Shahid Modarres Hospital and diagnosed with appendicitis based on their medical history and physical examinations. The exclusion criteria were age under 10 or above 45 years, normal appendix, advanced or perforated appendicitis, delayed appendectomy, diabetes, patients on chemotherapy, the ones receiving corticosteroids or antifungal drugs, immunodeficiency diseases, history of radiotherapy.

Intervention groups

In the first group, the subcuticular method was used to repair the surgical wound and in the second group, the transdermal method was employed.

Main outcome variables

Local infection; Wound dehiscence ; Level of pain ; Scar thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161217031440N1**

Registration date: **2018-09-27, 1397/07/05**

Registration timing: **retrospective**

Last update: **2018-09-27, 1397/07/05**

Update count: **0**

Registration date

2018-09-27, 1397/07/05

Registrant information

Name

Barmak Gholizadeh

Name of organization / entity

Shahid beheshti university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 2298 6403

Email address

b_gholizadeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2018-03-21, 1397/01/01

Trial completion date

empty

Scientific title

Comparison of Subcuticular and Transdermal Appendectomy Repairs in appendectomy patients; a Randomized Clinical Trial

Public title

Comparison of Subcuticular and Transdermal Appendectomy Repairs; a Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The inclusion criteria were the patients with appendicitis symptoms referred to the Emergency Department of Shahid Modarres Hospital and diagnosed with appendicitis based on their medical history and physical examinations.

Exclusion criteria:

Age under 10 or above 45 years Normal appendix Advanced or perforated appendicitis Delayed appendectomy Diabetes Patients on chemotherapy The ones receiving corticosteroids or antifungal drugs Immunodeficiency diseases History of radiotherapy

Age

From **10 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **251**

Actual sample size reached: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by random table

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Third Floor, School of Medicine, Aarabi st., Yaman st., Shahid Chamran hwy.

City

Tehran

Province

Tehran

Postal code

193954719

Approval date

2017-10-14, 1396/07/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.449

Health conditions studied

1

Description of health condition studied

Appendicitis

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

Primary outcomes

1

Description

Local infection

Timepoint

1 week after surgery

Method of measurement

Signs such as inflammation and purulent discharge from incision line

2

Description

Wound dehiscence

Timepoint

1 week after surgery

Method of measurement

Wound dehiscence which determined by suegeon

3

Description

Level of pain

Timepoint

1 week after surgery

Method of measurement

Level of pain based on verbal rating scale (VRS) No pain 0 ; Mild pain 1 ; Moderate pain 2; Severe pain 3

4

Description

Scar thickness, mm

Timepoint

1 month after surgery

Method of measurement

Using a ruler on mm

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the subcuticular method, the subcutaneous tissue was repaired with absorbable stitches and then, the skin was restored subcutaneously with 3-0 nylon stitches.

Category

Treatment - Surgery

2

Description

Control group: In the transdermal method, the subcutaneous tissue was repaired with absorbent stitches and then the skin was restored simply with 3-0 nylon stitches.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres medical center

Full name of responsible person

Barmak Gholizadeh

Street address

Shahid Modarres medical center, Saadat abad st.

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1998734383

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zargi

Street address

3rd Floor, School of Medicine, Arabi st., Yaman st.,
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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Barmak Gholizadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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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

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

Title and more details about the data/document

It is not yet known if there will be a plan to make this available

When the data will become available and for how long

It is not yet known if there will be a plan to make this available

To whom data/document is available

It is not yet known if there will be a plan to make this available

Under which criteria data/document could be used

It is not yet known if there will be a plan to make this available

From where data/document is obtainable

It is not yet known if there will be a plan to make this available

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

It is not yet known if there will be a plan to make this available

Comments