

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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.

##### City

tehran

##### Province

Tehran

##### Postal code

1998734383

##### Phone

+98 21 2208 3109

##### Email

barmak.gholizadeh@gmail.com

## 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.,  
Shahid Chamran hwy.

##### City

tehran

#### Province

Tehran

#### Postal code

193954719

#### Phone

+98 21 2243 9781

#### Email

Mpajouhesh@sbmu.ac.ir

#### 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

##### Street address

Shahid Modarres hospital, Saadat Abad st.

##### City

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## Person responsible for scientific inquiries

#### Contact

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Shahid Beheshti University of Medical Sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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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**