

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Comparative study of the effect of subcutaneous washing with serum gentamicin and normal serum saline in preventing wound infection following appendectomy

#### Protocol summary

##### Study aim

The aim of this study is to determine the effect of subcutaneous washing with gentamicin serum in preventing wound infection following appendectomy.

##### Design

This study is a randomized, clinical trial that will be performed on 120 appendicitis patients referring to the Neyshabour 22 Bahman Hospital. First, patients will be examined for inclusion criteria and Exclusion criteria. Then, eligible patients will be selected by available sampling method. They will be randomly divided into two groups: normal saline and gentamicin.

##### Settings and conduct

This study is a randomized, clinical trial that will be performed on 120 appendicitis patients referring to the Neyshabour 22 Bahman Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Appendicitis candidate; age range 10-50 years old; resident of Neishabur; and absence of cardiovascular and diabetes; Exclusion criteria: Complications of appendicitis; Corticosteroid use; Smoking and obesity.

##### Intervention groups

In the normal saline group after removing the appendix, half-liter of normal saline will be used to wash the subcutaneous tissue. In the gentamicin group, after removing the appendix, the subcutaneous tissue will be washed with normal saline and gentamicin (half a liter of normal saline with 80 mg gentamicin).

##### Main outcome variables

The researcher after operation will examines patients for ulcerative infection as long as they are admitted to the hospital by checking and checklist form with the physician verifying, and from the time of discharge to 30 days after surgery with telephoning control. It is also requested that patients to refer to the hospital's clinic in case any abnormal signs so that the doctor can disclose

the presence or absence of infection.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170921036302N4**

Registration date: **2018-05-11, 1397/02/21**

Registration timing: **retrospective**

Last update: **2018-05-11, 1397/02/21**

Update count: **0**

##### Registration date

2018-05-11, 1397/02/21

##### Registrant information

##### Name

sadigheh Khalili Shomia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4401 8328

##### Email address

khalilis@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Governmental

##### Expected recruitment start date

2017-04-25, 1396/02/05

##### Expected recruitment end date

2017-08-27, 1396/06/05

##### Actual recruitment start date

2017-04-25, 1396/02/05

##### Actual recruitment end date

2017-08-27, 1396/06/05

**Trial completion date**

empty

**Scientific title**

Comparative study of the effect of subcutaneous washing with serum gentamicin and normal serum saline in preventing wound infection following appendectomy

**Public title**

Effect of subcutaneous washing with gentamicin serum on prevention of wound infection following appendectomy

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Appendicitis candidate Age range 10-50 years old Resident of Neishabur Absence of cardiovascular and diabetes

**Exclusion criteria:**

Complications of appendicitis Taking corticosteroids Smoking and obesity

**Age**

From **10 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**  
More than 1 sample in each individual  
Number of samples in each individual: **1**  
One example  
Actual sample size reached: **120**  
More than 1 sample in each individual  
Actual sample size in each individual: **1**  
One example

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants in the study will be selected by available sampling method then will be divided to intervention and control groups by randomization software (www.randomizer.com).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Sabzevar University of Medical Sciences

**Street address**

Collegiate Paradise, Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9613873136

**Approval date**

2017-03-13, 1395/12/23

**Ethics committee reference number**

ir.medsab.rec.1395.134

**Health conditions studied**

1

**Description of health condition studied**

Infections of the skin and subcutaneous tissue

**ICD-10 code**

L00-L08

**ICD-10 code description**

Infections of the skin and subcutaneous tissue

**Primary outcomes**

1

**Description**

Incidence of wound infection after appendectomy

**Timepoint**

After surgery up to 30 days after discharge

**Method of measurement**

Check list

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

In the normal saline group after removing the appendix, half-liter of normal saline will be used to wash the subcutaneous tissue.

**Category**

Prevention

2

**Description**

In the gentamicin group, after removing the appendix, the subcutaneous tissue will be washed with normal saline and gentamicin (half a liter of normal saline with 80 mg gentamicin).

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

22 Bahman Neyshabour Hospital

**Full name of responsible person**

Maryam Ebadi

**Street address**

22 Bahman Hospital, Imam Khomeini Square, Neyshabour

**City**

Neyshabour

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 6433 3622

**Email**

SHOMIA@YMAIL.COM

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Sabzevar University of Medical Sciences

**Full name of responsible person**

Doctor Fereshteh Ghorat

**Street address**

Collegiate Paradise, Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

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**Province**

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**Phone**

+98 51 4401 8302

**Email**

SHOMIA@YMAIL.COM

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Sadigheh Khalili Shomia

**Position**

Master of Science in Nursing, Faculty Member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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shomia@ymail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

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**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

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**Province**

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**Postal code**

9613873136

## 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