

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

9613873136

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

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

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

Street address

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

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 8328

Fax**Email**

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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9613873136
Phone
+98 51 4401 8328
Fax
Email
shomia@ymail.com
Web page address

Phone
+98 51 4401 8328
Fax
Email
shomia@ymail.com
Web page address

Person responsible for updating data

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