

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of preoperative antiseptic showering to prevent surgical site infection, in patients who underwent elective inguinal hernia surgery.

Protocol summary

Study aim

To evaluate the incidence of surgical site infection in intervention and control groups.

Design

The aim of this study was to evaluate the effectiveness of antiseptic shower in prevention of surgical site infection. It is a clinical trial with control groups with parallel groups and double blinded. Simple randomization is done by using a random number table. The sample size is 300 people.

Settings and conduct

This study will evaluate the effect of antiseptic shower on prevention of postoperative infection in patients who will refer to Kowsar Hospital in Sanandaj who are diagnosed with inguinal hernia for elective surgery. Patients are divided into three groups. It is two-way blinded, participants, researcher and followers of the outcome, as well as statistical analyzer are unaware of grouping.

Participants/Inclusion and exclusion criteria

All patients who are undergoing elective surgery in the range of 5 to 75 years old with an inguinal hernia diagnosis will be included in the study. People with immunocompromised, infections or inflammation in the site operation, history of allergy to antiseptic agents and emergency surgery or strangulated hernia will be excluded from the study.

Intervention groups

The first group is the patient who will receive antiseptic shower with a 4% chlorhexidine solution before the operation. The second group is the patients who will receive a regular detergent before surgery. The third group is patients who do not receive any type of washing before the surgery.

Main outcome variables

Surgical site infection within a period of 30 days after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190224042819N1**

Registration date: **2019-07-24, 1398/05/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-24, 1398/05/02**

Update count: **0**

Registration date

2019-07-24, 1398/05/02

Registrant information

Name

Ebrahim Khajeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3377 9901

Email address

ebrahim.khajeh@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of preoperative antiseptic showering to prevent surgical site infection, in patients who underwent elective inguinal hernia surgery.

Public title

Effect of antiseptic showering before surgery on preventing surgical site infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Elective inguinal hernia surgery Age range from 5 to 75 years old

Exclusion criteria:

Immunocompromised patients Emergency surgery Strangulated inguinal hernia Wound or inflammation at surgery site Allergy to antiseptic agents

Age

From **5 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study we will use table of random numbers for simple randomization method. Unit of randomization is individual. Each patient who came to hospital for elective inguinal hernia surgery, will receive a code at the time of admission. Based on their code they will allocate to one of three different groups of study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be allocated in one of the three study groups based on the admission code. In the ward, the nurse provides the intervention (antiseptic shower or placebo) based on the patient code. At the time of the operation, the surgeon has no information about the grouping of patients. After the discharge of the patients, the investigator will follow-up the outcome (surgical site infection) which also is unaware of the grouping of the participants. Finally, the data analyst will evaluate the outcomes in three groups without knowing their segmentation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan university of medical sciences

Street address

Sanandaj, Pasdaran Ave, Kurdistan university of medical sciences

City

sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2019-05-01, 1398/02/11

Ethics committee reference number

IR.MUK.REC.1398.023

Health conditions studied

1

Description of health condition studied

Surgical site infection

ICD-10 code

T81.4

ICD-10 code description

Infection following a procedure

Primary outcomes

1

Description

Surgical site infections (SSIs) are defined as infections occurring up to 30 days after surgery and affecting either the incision or deep tissue at the operation site.

Timepoint

period of 30 days after surgery

Method of measurement

inspection and examination of surgery site

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who receive antiseptic shower with a 4% chlorhexidine solution before surgery.

Category

Prevention

2

Description

Control group: Patients who bath with regular detergents before surgery.

Category

Placebo

3

Description

Control group: Patients who do not receive any shower before surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Ebrahim Khajeh

Street address

Pasdaran Ave, Sanandaj, Kurdistan university of medical sciences

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Phone

+98 87 3366 4645

Fax

+98 87 3366 4643

Email

Ebrahim.khajeh@muk.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Farzin Rezaei

Street address

Pasdaran Ave

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Phone

+98 87 3366 4645

Email

frrezaie@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Khajeh

Position

Rezident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Pasdaran Ave, Kowsar hospital

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Phone

+98 87 3366 4645

Email

Ebrahim.khajeh@muk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Khajeh

Position

Rezident

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General Surgery

Street address

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City

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Province

Kurdistan

Postal code

6617713446

Phone

+98 87 3366 4645

Email

Ebrahim.khajeh@muk.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

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Street address

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Ebrahim.khajeh@muk.ac.ir

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

Except for personal information, the total collected data relates to the participants in the study, as well as the outcome of the intervention will be shared.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

There is no other criteria needed.

From where data/document is obtainable

Contact the researcher: Dr. Ebrahim Khajeh Mobile: 98 917 361 7490 Email: Ebrahim.khajeh@muk.ac.ir Ebrahim.khajeh@gmail.com

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

Applicants will initially submit their application to the researcher and, if approved by the Kurdistan University of Medical Sciences, the information will be provided to them within a period of about one month.

Comments