

# 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. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Public title</b>                                                                                                                             | Effect of antiseptic showering before surgery on preventing surgical site infection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Purpose</b>                                                                                                                                  | Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Inclusion/Exclusion criteria</b>                                                                                                             | <b>Inclusion criteria:</b><br>Elective inguinal hernia surgery Age range from 5 to 75 years old<br><b>Exclusion criteria:</b><br>Immunocompromised patients Emergency surgery<br>Strangulated inguinal hernia Wound or inflammation at surgery site Allergy to antiseptic agents                                                                                                                                                                                                                                                                                                  |
| <b>Age</b>                                                                                                                                      | From <b>5 years</b> old to <b>75 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Gender</b>                                                                                                                                   | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Phase</b>                                                                                                                                    | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Groups that have been masked</b>                                                                                                             | <ul style="list-style-type: none"> <li>Investigator</li> <li>Outcome assessor</li> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Sample size</b>                                                                                                                              | Target sample size: <b>300</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Randomization (investigator's opinion)</b>                                                                                                   | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Randomization description</b>                                                                                                                | 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.                                                                                                                                                                                                                                                   |
| <b>Blinding (investigator's opinion)</b>                                                                                                        | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Blinding description</b>                                                                                                                     | Participants will be allocat 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. |
| <b>Placebo</b>                                                                                                                                  | Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Assignment</b>                                                                                                                               | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Other design features</b>                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Secondary Ids</b>                                                                                                                            | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

|                                                |                                                                                                                                                                         |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ethics committees</b>                       |                                                                                                                                                                         |
| <b>1</b>                                       |                                                                                                                                                                         |
| <b>Ethics committee</b>                        |                                                                                                                                                                         |
| <b>Name of ethics committee</b>                | Ethics committee of Kurdistan university of medical sciences                                                                                                            |
| <b>Street address</b>                          | Sanandaj, Pasdaran Ave, Kurdistan unversity of medical sciences                                                                                                         |
| <b>City</b>                                    | sanandaj                                                                                                                                                                |
| <b>Province</b>                                | Kurdistan                                                                                                                                                               |
| <b>Postal code</b>                             | 6617713446                                                                                                                                                              |
| <b>Approval date</b>                           | 2019-05-01, 1398/02/11                                                                                                                                                  |
| <b>Ethics committee reference number</b>       | IR.MUK.REC.1398.023                                                                                                                                                     |
| <b>Health conditions studied</b>               |                                                                                                                                                                         |
| <b>1</b>                                       |                                                                                                                                                                         |
| <b>Description of health condition studied</b> | Surgical site infection                                                                                                                                                 |
| <b>ICD-10 code</b>                             | T81.4                                                                                                                                                                   |
| <b>ICD-10 code description</b>                 | Infection following a procedure                                                                                                                                         |
| <b>Primary outcomes</b>                        |                                                                                                                                                                         |
| <b>1</b>                                       |                                                                                                                                                                         |
| <b>Description</b>                             | 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. |
| <b>Timepoint</b>                               | period of 30 days after surgery                                                                                                                                         |
| <b>Method of measurement</b>                   | inspection and examination of surgery site                                                                                                                              |
| <b>Secondary outcomes</b>                      | empty                                                                                                                                                                   |
| <b>Intervention groups</b>                     |                                                                                                                                                                         |
| <b>1</b>                                       |                                                                                                                                                                         |
| <b>Description</b>                             | Intervention group: Patients who receive antiseptic shower with a 4% chlorhexidine solution before surgery.                                                             |
| <b>Category</b>                                | 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

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**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

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**Province**

Kurdistan

**Postal code**

6617713446

**Phone**

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**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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

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

Sanandaj University of Medical Sciences

**Full name of responsible person**

Ebrahim Khajeh

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Rezident

**Latest degree**

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**Phone**

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**Email**

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**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**