

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Comparison of the Incidence and Severity of Wound Infection to 2 Methods of Primary Prep Washing with 70% Alcohol and Normal Saline in Patients Undergoing Orthopedic Surgery

Protocol summary

Study aim

The purpose of this study is to compare the incidence and severity of wound infection with two methods of washing the primary orthopedic prep area with 70% alcohol and normal saline.

Design

This is a three-way blind randomized clinical trial by block method with parallel intervention and control groups on 190 patients.

Settings and conduct

This study will be conducted in Kowsar Sanandaj Hospital in Iran. At first, patients who meet the inclusion criteria are purposefully included in the study; Then they will be randomly assigned to two intervention and control groups in the form of double blocks. The method of blinding the study is three-blind. The participants, the second researcher as the outcome assessor and data analyst will be unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

Participants will be included in the study based on the following criteria. Elective orthopedic surgery volunteer of the upper limb; volunteer to participate in research; Shaving hair before surgery; The patient's body mass index is less than 30; lack of skin damage in the surgical area due to trauma; Absence of underlying, infectious diseases; Immune system disorders, skin allergies; Burns and previous surgery in the prep area and no vascular problems in the organ under surgery

Intervention groups

In both intervention and control groups, the surgical site will be prepped with brown betadine diluted with normal saline for three minutes. Then, in the intervention group, the primary prep area is washed with 70% alcohol and in the control group with normal saline.

Main outcome variables

The severity of wound infection in the two groups will be measured based on the comparison of the average score

obtained from the standard Assepsis index tool up to two weeks after the patient's discharge from the hospital. A score lower than 10 means no wound infection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160301026861N3**

Registration date: **2023-04-24, 1402/02/04**

Registration timing: **retrospective**

Last update: **2023-04-24, 1402/02/04**

Update count: **0**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name

Jamal Seidi

Name of organization / entity

Kurdistan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2022-10-12, 1401/07/20

Actual recruitment start date

2020-04-08, 1399/01/20
Actual recruitment end date
 2023-03-11, 1401/12/20
Trial completion date
 2023-03-11, 1401/12/20

Scientific title
 The Comparison of the Incidence and Severity of Wound Infection to 2 Methods of Primary Prep Washing with 70% Alcohol and Normal Saline in Patients Undergoing Orthopedic Surgery

Public title
 Comparison of the effect of two methods of primary washing of the area disinfected with brown betadine with 70% alcohol and normal saline on the incidence and severity of postoperative wound infection

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The patient is a volunteer for elective orthopedic surgery of the upper limb The patient is a volunteer to participate in the research The hair in the surgical area must be shaved before the operation The body mass index of the patient is less than 30
Exclusion criteria:
 There should be no skin damage in the surgical area due to trauma The patient does not have any underlying diseases or skin allergies The patient does not have burns or previous surgery in the prep area The patient does not have vascular problems in the organ under surgery The patient does not have diseases related to the immune system and infectious diseases The patient does not have digestive or blood diseases

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
 Target sample size: **190**
 Actual sample size reached: **190**

Randomization (investigator's opinion)
 Randomized

Randomization description
 At the beginning of the study and based on the entry criteria, patients who meet the conditions for entry into the study are entered into the study. Then, considering the importance of random assignment in clinical trial studies to control possible confounders, the samples are randomly assigned to each of the intervention or control groups in the form of a double block.

Blinding (investigator's opinion)
 Triple blinded

Blinding description

The method of blinding the study is three-blind. Patients undergoing orthopedic surgery as research samples will not know the type of intervention. Before the study, from an ethical point of view, the samples will be informed that one of two types of intervention may be done for them, and written consent will be obtained from them. The first researcher in the intervention and control group performs the necessary interventions. The second researcher measures the incidence and severity of wound infection after surgery without knowing the type of intervention and the groups; Therefore, as a second person, he will be blind to the study. Also, the statistical consultant as a data analyst will be unaware of the groups; therefore, he will be considered as the third person blinded to the study.

Placebo

Not 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

Pasdaran Blvd; Faculty of Nursing and Midwifery; Kurdistan University of Medical Sciences, Sanandaj, Iran

City

Sanandaj

Province

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Postal code

6617713446

Approval date

2019-12-24, 1398/10/03

Ethics committee reference number

IR.MUK.REC.1398.222

Health conditions studied

1

Description of health condition studied

Primary prep area of patients candidates for elective orthopedic surgery of the upper limbs

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The incidence of wound infection after surgery with a score higher than ten from the wound evaluation and the absence of wound infection with a score lower than 10 will be measured by the ASEPSIS INDEX tool after orthopedic surgery.

Timepoint

It will be measured once. The symptoms of wound infection will be monitored from the time after surgery until two weeks after discharge from the hospital, and on the 14th day after discharge, the scores obtained from the Asepsis index tool will be collected.

Method of measurement

Based on the ASEPSIS INDEX tool, evaluation of wound healing after surgery including; Complementary antibiotic therapy (0-10 points), redness of the wound at the surgical site (0-5 points), serous discharge from the surgical site (0-5 points), deep disintegration of the wound (0-10 points), culture from the wound site and isolation of bacteria (0-10 points) Wound debridement under general anesthesia (0-10 points), drainage of purulent wound secretions under local anesthesia, purulent exudate (0-10 points), hospitalization for more than 14 days (0-5 points). The maximum score will be 70 and the minimum score will be zero. A score less than ten means complete healing of the wound and no wound infection. A score higher than ten means wound infection.

2

Description

The severity of wound infection after surgery will be determined based on the ASEPSIS INDEX standard tool. Based on this tool, a score of 0-10 indicates complete healing of the wound, a score of 11-20 indicates impaired wound healing, a score of 21-30 indicates partial wound infection, a score of 31-40 indicates moderate wound infection, and a score greater than 40 indicates severe wound infection.

Timepoint

It will be measured once. The symptoms of wound infection will be monitored from the time after surgery until two weeks after discharge from the hospital, and on the 14th day after discharge, the scores obtained from the Asepsis index tool will be collected.

Method of measurement

In this study, the average scores obtained from the ASEPSIS INDEX standard tool will be compared in two intervention and control groups.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The surgical site must be completely

shaved. The surgical area will be prepped with 5.7% betadine brown diluted with normal saline for three minutes. After the initial prep, betadine will be brown on the skin surface for two minutes. Then the surgical site is washed with 70% alcohol until the skin surface is free of betadine. Wait until the alcohol dries on the surface of the skin. After the intervention, secondary prep will be done with betadine 10% and with the help of three gauzes and for at least five minutes.

Category

Treatment - Surgery

2

Description

Control group: the surgical site must be completely shaved. The surgical area will be prepped with 7.5% brown betadine diluted with normal saline for three minutes. After the initial prep, brown will be on the skin surface for two minutes. Then, the surgical site is washed with normal saline until the skin surface is free of betadine. Then, using a sterile towel, the primary prep area will be dried. . After washing or normal saline serum and drying, secondary prep of the surgical area will be done again with betadine 10% and with the help of three gauzes and for at least five minutes.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital affiliated to Kurdistan University of Medical Sciences

Full name of responsible person

Behzad Gholamveisi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

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Pasdarán Blvd; Deputy of research and technology;
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Research@muk.ac.ir

Web page address

<https://research.muk.ac.ir/Page?pageld=60>

Grant name

Research project contract with Kurdistan University of
Medical Sciences No. 222/1398 in the amount of twenty
one million Rials

Grant code / Reference number

1805003000

**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

Jamal Seidi

Position

Associate Professor of Nursing and Director of
Operating Room Department of Kurdistan University
of

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

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Person responsible for updating data

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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

Results of data analysis

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in meta-analysis, systematic review and compilation of clinical guidelines

From where data/document is obtainable

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

Written and valid request by e-mail
jamal.seidi@yahoo.com

Comments