

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the prep of the surgical location with betadine 10% versus chlorhexidine gluconate 4% on the incidence rate and the severity of wound infection after upper limb orthopedic elective surgery: a double-blind randomized clinical trial

Protocol summary

Study aim

Comparison of the prep of the surgical location with betadine 10% versus chlorhexidine gluconate 4% on the incidence rate and the severity of wound infection after upper limb orthopedic elective surgery

Design

This is a randomized clinical trial, in which 140 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are a candidate for upper limb orthopedic elective surgery and will refer to Kosar Hospital in Sanandaj City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18 to 60 years old; candidate for upper limb orthopedic elective surgery; body mass index less than 30; normal white blood cell count.
Exclusion criteria: open fracture; history of upper limb surgery; presence of scar on the upper limb; affected with infectious diseases; diabetes or vascular disorders; immunodeficiency; taking immunosuppressive drugs; using alcohol or smoking cigarette.

Intervention groups

Intervention group: prep of the surgical location with chlorhexidine gluconate 4% for 3 minutes. Control group: prep of the surgical location with betadine 10% for 3 minutes.

Main outcome variables

The incidence rate of wound infection; the severity of wound infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N315**

Registration date: **2019-10-30, 1398/08/08**

Registration timing: **prospective**

Last update: **2019-10-30, 1398/08/08**

Update count: **0**

Registration date

2019-10-30, 1398/08/08

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2021-07-03, 1400/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the perp of the surgical location with betadine 10% versus chlorhexidine gluconate 4% on the incidence rate and the severity of wound infection after upper limb orthopedic elective surgery: a double-blind randomized clinical trial

Public title
Comparison of the perp of the surgical location with betadine 10% versus chlorhexidine gluconate 4% on the incidence rate and the severity of wound infection after upper limb orthopedic elective surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age:18 to 60 years old Candidate for upper limb orthopedic elective surgery Body mass index less than 30 Normal white blood cell count
Exclusion criteria:
 Open fracture History of upper limb surgery Presence of scar on the upper limb Affected with infectious diseases Diabetes or vascular disorders Immunodeficiency Taking immunosuppressive drugs Using alcohol or smoking cigarette

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sanadaj University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Sanadaj University of Medical Sciences, Pasdaran Ave

City

Sanandaj

Province

Kurdistan

Postal code

6617715175

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.MUK.REC.1398.069

Health conditions studied

1

Description of health condition studied

Surgical wound infection

ICD-10 code

T81.4

ICD-10 code description

Infection following a procedure

Primary outcomes

1

Description

The incidence rate of wound infection

Timepoint

One week after surgery

Method of measurement

Thorough physical examination

2

Description

The severity of wound infection

Timepoint

One week after surgery

Method of measurement

By Asepsis index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Perp of the surgical location with chlorhexidine gluconate 4% for 3 minutes

Category

Treatment - Surgery

2

Description

Control group:Perp of the surgical location with betadine 10% for 3 minutes

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital in Sanandaj City

Full name of responsible person

Behzad Gholamveisi

Street address

Kosar Hospital, Bohanedin Hamdi Ave.

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66617983476

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Ebrahim Ghaderi

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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

Behzad Gholamveisi

Position

Master of Operating Room

Latest degree

Master

Other areas of specialty/work

General Surgery

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School of Paramedicine, Sanadaj University of Medical Sciences, Pasdaran Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Master of Operating Room

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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