

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of using wet dressing with normal saline on infection, scar and healing process of surgical wound in patients undergoing orthopedic surgery

Protocol summary

Study aim

Determining the effect of using wet dressing with normal saline on infection, scar and the healing process of surgical wound in patients undergoing orthopedic surgery and comparing it with the routine method.

Design

A clinical trial with two intervention and control groups. A blind strain, randomized with a random number table. Phase 3. On 100 patients.

Settings and conduct

In the intervention group, from the day of surgery to the seventh, during the dressing change, a gauze soaked in normal saline is used. While in the control group, the routine method is used for dressing the surgical wound. The wound will be evaluated by the doctor and the researcher on days 3, 7, 13 and 21 after the surgery. and to evaluate the checklists for checking scars (Vancouver) and checklists (REEDA) as well as regarding the definite diagnosis of infection, from inflamed and exuding wounds directly and through sterile methods by sterile swap sampling and from blood environments, EMB and chocolate agar will be used to check for microbial contamination. The location of the study is Imam Ali (AS) hospital in Bojnoord. Also, the person who prepares and examines the culture samples does not know whether the patient is in the intervention group or the control group.

Participants/Inclusion and exclusion criteria

the absence of symptoms of infection in the surgical area before the intervention, a definitive diagnosis of orthopedic surgery for patients, having diabetes, and not having a history of drug abuse.

Intervention groups

In the intervention group, from the day of surgery to the 7 day, during the dressing change, a gauze is used that is completely soaked in normal saline (0.9% isotonic solution of chlorosodium) and then the excess liquid is

removed by fully observing the aseptic principles. While in the control group, the routine method is used for surgical wound dressing

Main outcome variables

infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220703055358N1**

Registration date: **2022-07-30, 1401/05/08**

Registration timing: **prospective**

Last update: **2022-07-30, 1401/05/08**

Update count: **0**

Registration date

2022-07-30, 1401/05/08

Registrant information

Name

Fatemeh Imani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 58 3225 7646

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f.imani@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of using wet dressing with normal saline on infection, scar and healing process of surgical wound in patients undergoing orthopedic surgery

Public title

Investigating the effect of using wet dressing with normal saline on infection, scar and healing process of surgical wound

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Absence of symptoms of infection in the surgical area before the intervention not having history of drug abuse not having diabetes definitive diagnosis of orthopedic surgery for patientsno

Exclusion criteria:

Surgical site infection

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is designed as a simple randomization with an individual random unit, and the randomization tool is a table of random numbers

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who prepares the culture samples does not know whether the patient is in the intervention group or the control group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Bojnurd University of Medical Sciences

Street address

College of Nursing and Midwifery,Shahryar St.,

City

Bojnurd

Province

North Khorasan

Postal code

94176-96786

Approval date

2022-07-04, 1401/04/13

Ethics committee reference number

IR.NKUMS.REC.1399.017

Health conditions studied**1****Description of health condition studied**

infection

ICD-10 code

B99.9

ICD-10 code description

Unspecified infectious disease

Primary outcomes**1****Description**

infection

Timepoint

Sampling from the surgical wound at the beginning of the study and days 3, 7, 13 and 21 after intervention.

Method of measurement

Sampling by sterile swap and from blood, EMB and chocolate agar media

Secondary outcomes**1****Description**

Oscar

Timepoint

At the beginning of the study, days 3, 7, 13 and 21 after the intervention

Method of measurement

Oscar Checklist (Vancouver)

2**Description**

recovery process

Timepoint

At the beginning of the study, days 3, 7, 13 and 21 after the intervention

Method of measurement
Recovery Checklist (REEDA)

Intervention groups

1

Description

Intervention group: Intervention group: From the day of surgery to the seventh, during the dressing change, a gauze is used that is completely soaked in normal saline (0.9% isotonic solution of chlorosodium) and then the excess liquid is removed with full compliance with aseptic principles. The wound will be evaluated by the doctor and the researcher on the 3rd, 7th, 13th and 21st days after the surgery. and to evaluate the checklists for checking the scar (Vancouver) and the checklist for checking the recovery process (REEDA) also in relation to the definite diagnosis of infection, sampling from inflamed and exuding wounds directly and through sterile methods using sterile swaps and from the environments Blood, EMB and chocolate agar will be used to check for microbial contamination.

Category

Treatment - Other

2

Description

Control group: From the day of surgery to the seventh day during the dressing change, the routine method (cleaning the wound using betadine and then drying it) is used for dressing the surgical wound. The wound will be evaluated by the doctor and the researcher on the 3rd, 7th, 13th and 21st days after the surgery. and to evaluate the checklists for checking the scar (Vancouver) and the checklist for checking the recovery process (REEDA) also in relation to the definite diagnosis of infection, from inflamed and exuding wounds directly and through sterile methods by sterile swap sampling and from the environments Blood, EMB and chocolate agar will be used to check for microbial contamination.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali (AS) Bojnourd educational and research center

Full name of responsible person

Fatemeh Imani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Fatemeh Imani

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable