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 chlorsodium) 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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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 chlorsodium) 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) Bojnoord educational and research center
Full name of responsible person
Fatemeh Imani
Street address
College of Nursing and Midwifery،Shahryar St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Dr. Amir Ali Garhami
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Shahyar St
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modiriat.pajoheshi@gmail.com
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
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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