Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The Effect of of Vancomycin powder and Povidon-Iodine in the Prevention of Wound infection in Open Lower-limb Fractures Undergoing Open Reduction and Internal Fixation

Protocol summary

Study aim
Prevention of wound infection in patients with open fractures undergoing internal fixation surgery

Design
A clinical trial with two control and intervention groups, with parallel, three-blind, randomized, sample size 40, a random number table will be used for randomization

Settings and conduct
This study will be performed on patients with open type 1 and 2 gastillo-Anderson fractures The present study will be performed in Ali Ibn Abitaleb (AS) Hospital in Rafsanjan. Methods: In both control and intervention groups, first the initial preparation will be done using 7% betadine solution for 5 minutes. Then, for secondary skin preparation before surgery, in the intervention group, 2 grams of vancomycin powder in the amount of 2 grams is also used. In the control group, however, the skin in the second stage will be prepared using only 10% betadine. The study is of the 3-blind type. The patient, the researcher, and the analyzers are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria initially include those with open fractures between the ages of 18 and 65. Also, their body mass index should be in the normal range and they should not have underlying and autoimmune diseases

Intervention groups
In both control and intervention groups, initial preparation will be performed using 5% betadine solution for 5 minutes. Then, for secondary skin preparation before surgery, in the intervention group, 2 grams of vancomycin powder in the amount of 2 grams is used together with betadine. In the control group, however, the skin in the second stage will be prepared using only 10% betadine.

Main outcome variables
rate of infection; The rate of use of injectable and oral antibiotics

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211023052845N1**
Registration date: **2021-12-20, 1400/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-20, 1400/09/29**
Update count: **0**

Registration date
2021-12-20, 1400/09/29

Registrant information

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Yaser Abolhasani Heydarabad

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of of Vancomycin powder and Povidon-Iodine in the Prevention of Wound infection in Open Lower-limb Fractures Undergoing Open Reduction and Internal Fixation

Public title

Evaluation of the effect of vancomycin and betadine on wound infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of open fracture and the need for open reduction and internal fixation surgery The patient should not be referred to the operating room as a vital emergency and should be fasted for 8 hours before the operation Age between 18 and 65 years Having a body mass index between 18 and 25 Not pregnant during the study Lack of sensitivity to seafood No autoimmune diseases and immune system defects (Guillain-Barre, multiple sclerosis, immune deficiency syndrome, etc.) Not having any declining bone disease Do not take antibiotics one week before surgery No skin diseases No history of orthopedic and neurosurgery during the last 6 months Absence of cIII degree open fractures in Gastillo Anderson classification No smoking and drug addiction Lack of underlying and autoimmune diseases (diabetes, multiple sclerosis, immune deficiency syndrome, etc.) No previous allergy to antibiotics and disinfectants Informed consent

Exclusion criteria:

Intraoperative blood transfusion Unforeseen events before surgery such as cardiac arrest and death Patient death during study (within 30 days after surgery) Bleeding more than 200 cc Duration of surgery more than 2 hours Arbitrary use of antibiotics without a doctor's prescription The interval between going to the emergency room and surgery is more than 23 hours Reluctance to continue participating in research

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization The method of assigning people to two groups of control and intervention will be so that the researcher uses a random table of numbers. This table contains a set of masses of numbers that are produced without a specific pattern or order and completely randomly and It is shown as a table. The researcher will consider two columns A (intervention) and B (control). After that the researcher touches one of the table numbers randomly and without looking at the table. If the even number is placed under the finger, the even sample will be considered for column A (intervention group) and if the odd number is placed, will be considered for column B (control group). Until it reaches the desired sample size in each group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

completely, the purpose of the study will be explained to patients, and if they are satisfied, those who have criteria for entering and answer positively to the research proposal will enter the study. All patients will be explained how to intervene, but patients will have no information about whether they will be allocated in the control or intervention group, and after sampling and analyzing the data, Information is given for both groups to performance of ethic of research (single blind). The intervention is performed by the researcher but randomization of people is done by the researcher, expert colleague to determine the control group or intervention and the researcher is unaware of the process until the end of the sampling stage. Before the researcher enters the operation field, the solution, will be provided by the research colleague. It should be noted that Poidon Aidan solution alone, have the same color and odor as well as the combination of betadine and vancomycin, , and experiments have confirmed this (double-blind). The statistical analyzer and the data safety and monitoring committee have no information about which data belongs to which control or intervention group, and only the checklist that filled by the researcher during the evaluation and analysis of the data is provided to them (triple-blind).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی اصفهان

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Hezar Jarib

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8174673461

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.301

Health conditions studied

1

Description of health condition studied

Open Fractures in Limbs

ICD-10 code

T14.8

ICD-10 code description

Injury of unspecified body region

Primary outcomes

1

Description

Infection

Timepoint

The first, second, fourteenth and twenty-eighth days after surgery

Method of measurement

Visual scale analog and laboratory sampling

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, after primary skin prep with betadine 7%, for secondary prep, 10% betadine solution with vancomycin powder in the amount of 2 g is used and it will be done using 3 sterile sponge.

Category

Prevention

2

Description

Control group: Control group: In the control group, after primary skin prep with betadine 7%, for secondary prep, betadine 10% alone (routine method) is used using 3 sterile gases.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebn Abitaleb hospital

Full name of responsible person

Yaser Abolhasani Heydarabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Published with the necessary coordination
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available