Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of the duration of hemovac drain placement 24 hours vs. 48 hours after lower limb orthopedic surgeries on the rate of microbial contamination and clinical outcomes of patients

Protocol summary

Study aim
To compare the effect of removing Hemovac drains 24 hours versus 48 hours after lower limb orthopedic surgeries on drain microbial contamination, microbial diversity, surgical site infection, hematoma, wound dehiscence, pain severity, length of hospital stay, and overall clinical outcomes of patients.

Design
Clinical trial with control group and intervention group, with parallel groups, single-blind on 180 people. Completely randomized block method for randomization

Settings and conduct
This randomized, single-blind clinical trial (blind assessor) will be conducted on orthopedic patients at Imam Khomeini Hospital in Sari. Patients will be randomly divided into two groups: removal of the Hemovac drain within 24 hours or 48 hours after surgery. At the time of drain removal, the last 5 cm of the drain will be cut sterilely and sent to the laboratory for microbial culture and antibiogram. Microbial contamination, bacterial species, and clinical complications (infection, hematoma, wound dehiscence, pain, length of stay, and antibiotic change) will be compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Type of surgery, age over 18 years, all patients with drains with closed lower limb orthopedic surgery with internal fixation, considering the patient's BMI. Exclusion criteria: Inability to remove the drain in patients with persistent discharge, active infection before surgery, changing the drain site or disrupting its function, patient's lack of cooperation in post-operative follow-up

Intervention groups
In the intervention group, the drain will be removed after 24 hours, and in the control group, the hemovag drain will be removed after 48 hours.

Main outcome variables
Microbial contamination of the Hemovac drain tip

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251113067985N1**
Registration date: **2025-12-05, 1404/09/14**
Registration timing: **prospective**

Last update: **2025-12-05, 1404/09/14**
Update count: **0**

Registration date
2025-12-05, 1404/09/14

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-12-06, 1404/09/15
Expected recruitment end date
2026-04-26, 1405/02/06
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of the duration of hemovac drain placement 24 hours vs. 48 hours after lower limb orthopedic surgeries on the rate of microbial contamination and clinical outcomes of patients

Public title

Examining the best time to remove the drain (drainage tube) after lower limb bone and joint surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Type of surgery Age over 18 years All patients with drains with closed lower limb orthopedic surgery with internal fixation Considering patient BMI

Exclusion criteria:

Inability to remove drain in patients with persistent discharge Active infection before surgery Changing the location of the drain or disrupting its function Patient's lack of cooperation in post-surgical follow-up

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, samples were selected using simple random sampling. In this study, patients hospitalized in the orthopedic department who underwent orthopedic surgery of the lower extremities and had a hemovac drain inserted and met the conditions for entry into the study were listed. To allocate individuals to the control and intervention groups, a block randomization method was used to maintain a balance in the number of participants in the two groups. In this way, the patient list was numbered and random number generation software (Excel) was used. Small blocks of 4 or 6 people were created, the order within each block was randomly determined, and the patients were placed in the control and intervention groups in the same order, and finally 90 people were placed in the control group and 90 people in the intervention group without the researcher having any non-random interference in their selection or allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is single-blinded and the evaluator will be unaware of the grouping of the participants in the study. In this study, we will have two groups. In one group, the hemovac drain will be removed 24 hours after the operation and in the other group, the hemovac drain will be removed 48 hours after the operation. The allocation of patients to the study groups will be based on a randomized block design.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

No. 58, 14 Sabalan Alley, Phase one

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Province

Ardabil

Postal code

5619766744

Approval date

2025-11-20, 1404/08/29

Ethics committee reference number

IR.MAZUMS.REC.1404.427

Health conditions studied

1

Description of health condition studied

Lower limb orthopedic surgeries

ICD-10 code

Y79

ICD-10 code description

Orthopedic devices associated with adverse incidents

Primary outcomes

1

Description

Hemovac drain contamination

Timepoint

24 hours

Method of measurement

Antibiogram test (antibiotic resistance and sensitivity) based on CLSI protocol

Secondary outcomes

1

Description
Wound infection (temperature above 38 degrees, redness, pain, and discharge)
Timepoint
On days 14, 7, 3 and 21 after surgery
Method of measurement
Based on standard guidelines from the Centers for Disease Control and Prevention (CDC)

2

Description
Wound dehiscence
Timepoint
On days 14, 7, 3 and 21 after surgery
Method of measurement
Based on standard guidelines from the Centers for Disease Control and Prevention (CDC)

Intervention groups

1

Description
Intervention group: Intervention group: Drain will be removed 24 hours after surgery
Category
Prevention

2

Description
Control group: Intervention group: Drain will be removed 48hours after surgery
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Mazandaran 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

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Mazandaran University of Medical Sciences
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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