

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the outcome of intra-medullary nailing surgery in femoral shaft fractures with and without wound washing

Protocol summary

Registration timing: **prospective**

Study aim

Comparison of the outcome of intra-medullary nailing surgery in femoral shaft fractures with and without wound washing.

Last update: **2021-12-19, 1400/09/28**

Update count: **0**

Registration date

2021-12-19, 1400/09/28

Design

The study will be double blind and clinical trial. 64 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

Registrant information

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Name of organization / entity

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Settings and conduct

Patients candidate for intra-medullary nailing surgery in Valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-pathological femoral shaft fracture, age 15 to 65 years, lack of underlying disease such as diabetes and hypertension, both gender. Exclusion criteria: no follow-up, death

Expected recruitment start date

2022-01-02, 1400/10/12

Expected recruitment end date

2022-04-01, 1401/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: In this group, all the conditions of fullness and observation are observed first, and after the surgery of the operation area (muscles and bones), normal saline solution is washed in three layers of fascia and skin of the minister without washing. Control group: In this group, first all the conditions are observed, but unlike the previous group, after surgery and before closing the wound, the operation area will be completely cleansed with about one liter of normal saline solution.

Main outcome variables

Wound healing, fracture healing

Scientific title

Comparison of the outcome of intra-medullary nailing surgery in femoral shaft fractures with and without wound washing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211207053318N1**

Registration date: **2021-12-19, 1400/09/28**

Public title

outcome of intra-medullary nailing surgery in femoral shaft fractures with and without wound washing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non-pathological femoral shaft fracture age 15 to 65 years lack of underlying disease such as diabetes and hypertension Both gender

Exclusion criteria:

No follow-up Death

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients as well as the project data analyzer and the project assistant who is responsible for completing the questionnaires will be unaware of the division of patients into two groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-11-14, 1400/08/23

Ethics committee reference number

IR.ARAKMU.REC.1400.224

Health conditions studied

1

Description of health condition studied

Femoral shaft fractures

ICD-10 code

S72.0

ICD-10 code description

Fracture of neck of femur

Primary outcomes

1

Description

Improving fracture location

Timepoint

6 weeks, 3, 4 and 6 months after surgery

Method of measurement

Radiology examination

2

Description

Wound healing

Timepoint

2, 4 and 11 days after surgery

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, all the conditions of fullness and observation are observed first, and after the surgery of the operation area (muscles and bones), normal saline solution is washed in three layers of fascia and skin of the minister without washing.

Category

Treatment - Surgery

2

Description

Control group : In this group, first all the conditions are

observed, but unlike the previous group, after surgery and before closing the wound, the operation area will be completely cleansed with about one liter of normal saline solution.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr. Mohsen Parsi Khameneh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak 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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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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Latest degree

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Other areas of specialty/work

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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

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