

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effectiveness and outcome of antibiotic cemented nails with external fixators in patients with open long bone fractures Gustilo and Anderson type 3

Protocol summary

Study aim

Comparison of the results (complications and outcome) of antibiotic cemented nails with external fixators in patients with open long bone fractures Gustilo and Anderson type 3

Design

Two parallel groups of 35 patients non randomized with open long bone fractures of Gustilo and Anderson type 3 treated by custom made antibiotic cemented nail in intervention 1 group and external fixators in intervention 2 group.

Settings and conduct

Two packs of 40-gram bone cement powder and 2 grams of vancomycin were mixed by vacuum mixer. Then, the low viscous cement was injected into the chest tube. The injected cement must be bubble-free. Based on the natural shape of the bone, the chest tube was bowed. After the cement hardened, the chest tube was cut longitudinally. Afterward, the cement nail was polished. The bone's internal cortex was rimmed. Based on the standard operational technique for each bone, the antibiotic cement nail was inserted, and then the proper position was checked with C-arm. The proximal and distal parts of TEN were bent for easier removal External fixators were used for intervention 2 groups in operation room Taleghani Hospital Tehran

Participants/Inclusion and exclusion criteria

Patients entering Taleghani Hospital with long bone open fractures Gustilo and Anderson type 3 Exclusion criteria: Pregnancy, planning for pregnancy, breastfeeding, renal failure, allergy to vancomycin

Intervention groups

Using custom made antibiotic cemented mixed with vancomycin nail in intervention 1 group and external fixators in the intervention 2 group

Main outcome variables

Fracture union, infection, hospital stay and number of

surgical operations needed for healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039188N3**

Registration date: **2022-06-20, 1401/03/30**

Registration timing: **prospective**

Last update: **2022-06-20, 1401/03/30**

Update count: **0**

Registration date

2022-06-20, 1401/03/30

Registrant information

Name

Reza Zandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2560

Email address

reza.zandi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness and outcome of antibiotic cemented nails with external fixators in patients with open long bone fractures Gustilo and Anderson type 3

Public title

Comparison of the effectiveness and outcome of antibiotic cemented nails with external fixators in patients with open long bone fractures Gustilo and Anderson type 3

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Long bone open fractures type 3 Gustilo and Anderson

Exclusion criteria:

Pregnancy Planning for pregnancy Renal failure
Vancomycin allergy Breast feeding

Age

From **11 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization for 2 intervention groups, will done using software, similar random numbers for each group. The surgeon can not play a role in predicting treatment of the disease, and choosing the type of treatment. Random sequence will generate by software. All admitted patients will be placed in one of the groups according to the pre-determined code

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Vice-Chancellor in

Research Affairs - Shahid Beheshti University of Me

Street address

School of Medicine, Koodakyar street, Shahid
Shahriari Square, Chamran highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-05-15, 1401/02/25

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.087

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

Gustilo-Anderson type III lower open limb fractures

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hospitalization duration, Malunion, Nonunion, Infection

Timepoint

1 year

Method of measurement

By measuring ESR, CRP, and considering radiological and clinical features.

Secondary outcomes

empty

Intervention groups**1****Description**

Patients with Gustilo-Anderson type III lower open limb fractures treated with antibiotic cement nail primarily.

Category

Treatment - Surgery

2**Description**

Patients with Gustilo-Anderson type III lower open limb fractures treated with external fixator.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Reza Zandi

Street address

Taleghani hospital, erabi Ave, Teman Ave, Chamran highway

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Fax

+98 21 2243 2570

Email

taleghanihospital@sbmu.ac.ir

Web page address

<https://taleghani.sbmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Zandi

Street address

koodakyar street, shahid shahriari square, chamran highway, tehran, iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

Dean.medicalschool@sbmu.ac.ir

Web page address

<https://msp.sbmu.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Zandi

Position

associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Erabi Ave, yemen Ave, chamran highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2303 1111

Fax

+98 21 2243 2570

Email

Reza.zandi@sbmu.ac.ir

Web page address

<https://taleghani.sbmu.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Zandi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Erabi street, Yamen Ave, Chamran highway

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2303 1111

Fax

+98 21 2243 2570

Email

Reza.zandi@sbmu.ac.ir

Web page address

<https://taleghani.sbmu.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Zandi

Position

associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Erabi street, Yamen Ave, chamran highway

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2303 1111

Fax

+98 21 2243 2570

Email

Reza.zandi@sbmu.ac.ir

Web page address

<https://taleghani.sbmu.ac.ir/>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The data will be provided to the applicant researcher after the article is published.

When the data will become available and for how long

2023

To whom data/document is available

All researchers

Under which criteria data/document could be used

At the request of the researcher

From where data/document is obtainable

Email to Dr, Reza Zandi

What processes are involved for a request to access data/document

After the email and the reason, the data is provided.

Comments

nothing