

# 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**

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**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

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Taleghani hospital, erabi Ave, Teman Ave, Chamran highway

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<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

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

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Dean.medicalschool@sbmu.ac.ir

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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**

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

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**Contact**

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**Position**

Associate professor

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Reza Zandi

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**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