# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Evaluation of effect of Teriparatide in the acceleration of comminuted fracture union of tibia and femural shaft

### Protocol summary

**Study aim**
Evaluation of effect of Teriparatide in the acceleration of comminuted fracture union of tibia and femural shaft

**Design**
A clinical trial with an intervention and control group with parallel groups, a blind strain, randomized with blocks of four (A, A, B, B) and on 56 patients, rand function of Excel software was used for randomization.

**Settings and conduct**
This study is a single-blind clinical trial study that will be conducted at Alborz University of Medical Sciences - Shahid Madani Medical Training Center. Patients who met the inclusion criteria after performing adduction and fixation surgery were randomly divided into two control groups and a study group who received 20 micrograms of triparatide (Sinopar) subcutaneously for six months. And the patients are evaluated monthly in terms of fusion by orthopedic and radiographic criteria, and finally they are evaluated in terms of time of fusion and return to initial function, and the obtained information is analyzed by SPSS26 software. that the analyst is blinded.

**Participants/Inclusion and exclusion criteria**
include criteria for patients: Having a fracture of the tibia and femur and not being allergic to triparatide and not having an underlying disease affecting the bone exclude criteria: 1. Under 18 and over 45 years old 2. Allergy to triparatide 3. Having a serious underlying disease such as uncontrolled diabetes, heart failure, kidney failure, etc.

**Intervention groups**
The study group received 20 micro grams of triparatide (Sinopar) subcutaneously for six months And the control group does not receive medication

**Main outcome variables**
Acceleration of union time of femoral shaft and tibia comminuted fractures; Accelerating the return to work and daily performance of these patients; Preventing reoperations of non-union of comminuted fractures of the femoral shaft and tibia; Avoiding the heavy costs of non-Union patients

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20221220056874N1**
Registration date: **2023-01-12, 1401/10/22**
Registration timing: **prospective**

Last update: **2023-01-12, 1401/10/22**
Update count: **0**

**Registration date**
2023-01-12, 1401/10/22

**Registrant information**

**Name**
Hamed Azadi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
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azadihamed70@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-02-20, 1401/12/01

**Expected recruitment end date**
2023-08-23, 1402/06/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
Evaluation of effect of Teriparatide in the acceleration of comminuted fracture union of tibia and femural shaft

**Public title**
Teriparatide in the acceleration of comminuted fracture

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Having comminuted fractured tibia and femural shaft Obtaining informed consent to participate in this study Being between 18-45 years old Not having osteoporosis that has been confirmed in the radiographies Not being allergic to triparatide If a person has previously used bisphosphonates, at least three months should pass after stopping their use, and then start triparatide. Not having a serious underlying disease such as uncontrolled diabetes, heart failure, kidney failure, etc. Not having Paget's disease, hypercalcemia for any reason, hyperparathyroidism No history of osteosarcoma

**Exclusion criteria:**
Under 18 and over 45 years old Allergy to triparatide Having a serious underlying disease such as uncontrolled diabetes, heart failure, kidney failure, etc. Having Paget's disease, hypercalcemia for any reason, hyperparathyroidism Having a history of osteosarcoma

**Age**
From **18 years** old to **45 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **52**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
They were randomly divided into triparatide and control groups. For this purpose, quadruple blocks (A, A, B, B) were created and two groups of people were formed in each block. These blocks are created randomly so that in each group, the number of people in the study phase is almost equal. Therefore, at each stage of the study, a block (the allocation of four marks within the block is random and there are many blocks) was randomly selected and then people were assigned to the relevant group according to the order in which they appeared in that block. . (A was the triparatide group, B was the control group).

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
The statistical analyst is unaware of the patient receiving the drug triparatide

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of Alborz University of Medical Sciences

**Street address**
Shahid Madani hospital, madani squ.

**City**
Karaj

**Province**
Alborz

**Postal code**
1234567891

**Approval date**
2022-12-03, 1401/09/12

**Ethics committee reference number**
IR.ABZUMS.REC.1401.252

## Health conditions studied

### 1

**Description of health condition studied**
comminuted fracture union of tibia and femural shaft

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Union of comminuted fracture of tibia and femural shaft fracture

**Timepoint**
Every month after prescribing the drug for up to six months

**Method of measurement**
Clinical sign and symptoms and radiographic signs

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: daily 20 micro grams of triparatide (Sinopar) subcutaneously for six months

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Madani hospital
**Full name of responsible person**
Hamed Azadi
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**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**
Karaj 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**
Karaj University of Medical Sciences
**Full name of responsible person**
Hamed Azadi
**Position**
orthopaedic resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Orthopedics
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## Person responsible for updating data

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**Latest degree**
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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**
Reluctance of researchers

**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