

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 femoral shaft

Protocol summary

Study aim

Evaluation of effect of Teriparatide in the acceleration of comminuted fracture union of tibia and femoral 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

+98 26 3442 7015

Email address

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 femoral shaft

Public title

Teriparatide in the acceleration of comminuted fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having comminuted fractured tibia and femoral 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 teriparatide If a person has previously used bisphosphonates, at least three months should pass after stopping their use, and then start teriparatide. 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 teriparatide
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 teriparatide 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 teriparatide 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 teriparatide

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 femoral shaft

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Union of comminuted fracture of tibia and femoral 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 teriparatide (Sinopar) subcutaneously for six months

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Shahid Madani hospital

Full name of responsible person

Hamed Azadi

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Web page address<https://abzums.ac.ir/>**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Arvin Najafi

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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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Full name of responsible person

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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