Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
+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 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
Street address
Madani squ.
City
Karaj
Province
Alborz
Postal code
1234567891
Phone
+98 26 3442 7001
Fax
+98 26 3442 6979
Email
A.najafi@abzums.ac.ir
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
Street address
Shahid madani hospital, Madani squ.
City
Karaj
Province
Alborz
Postal code
1234567891
Phone
+98 26 3442 7001
Email
A.najafi@abzums.ac.ir
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
Street address
Madani hospital, Madani squ
City
Karaj
Province
Alborz
Postal code
1234567891
Phone
+98 26 3447 4047
Email
Azadihamed70@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Arvin Najafi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Madani Hospital, Madani squ.
City
Karaj
Province
Alborz
Postal code
1234567891
Phone
+98 24 3442 7001
Email
parsmedicine@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Hamed Azadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

Street address
Madani hospital, Madani sque.

City
Karaj

Province
Alborz

Postal code
1234567891

Phone
+98 26 3442 7001

Email
Azadihamed70@gmail.com

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