

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the effect of the combination of Teriparatide and Calcium supplement in comparison with Calcium supplement alone on intertrochanteric fracture healing

Protocol summary

Study aim

The aim of this study was to assess the efficacy of teriparatide in the repair of intertrochanteric fractures.

Design

Clinical trial with control group, doubled blind, randomized, phase 3 on 80 patients. Random numbers produced by an internet site <https://www.random.org/> is used for randomization.

Settings and conduct

Study place: Orthopedic ward of Emam Hossein Hospital in Tehran. Type of blinding: Double blind. How to blind: Participant; they assume that all participants have received the intervention and are unaware of the other group. Outcome Assessor; A group of 2 orthopedic surgeons will evaluate radiography, fracture classification, reduction, fixation quality, and ionic process during the study without knowing the group of individuals, and will examine them separately, blinded, and separately using digital radiography. The opinion is examined by a third surgeon. Data Analyzer: Without knowing the details of the control and experimental groups, analyzed the data in 2 separate groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People over 50 with Intertrochanteric fractures; use Teriparatide for a period of 3 months after surgery; Vitamin D with normal serum levels. Non-inclusion criteria: unacceptable fracture reduction; multiple fractures; underlying conditions; self-medication that affects bone ;pathological fractures; absence of medical records

Intervention groups

Control group: patients undergoing gamma nail surgery and calcium supplementation alone. Intervention group: patients who undergo surgery with the Gamma nail technique and in addition to calcium supplementation, also receive teriparatide.

Main outcome variables

Duration (weeks) of repair of intertrochanteric fracture from the time of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201121049452N1**

Registration date: **2021-01-24, 1399/11/05**

Registration timing: **retrospective**

Last update: **2021-01-24, 1399/11/05**

Update count: **0**

Registration date

2021-01-24, 1399/11/05

Registrant information

Name

Behnam Navari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8602 5210

Email address

behnamtarinn@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of the combination of Teriparatide and Calcium supplement in comparison with Calcium supplement alone on intertrochanteric fracture healing

Public title
Effect of Teriparatide on Intertrochanteric Fractures Healing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People over 50 years old with intertrochanteric fractures use Teriparatide for a period of 3 months after surgery Vitamin D with normal serum levels
Exclusion criteria:
Teriparatide is prescribed before surgery Teriparatide is prescribed for less than 3 months Unacceptable fracture reduction Multiple fractures Underlying conditions, or self-medication that affects bone repair Contralateral pelvic fractures Pathological fractures Any anti-osteoporosis medication (except calcium and vitamin d tablets) Deficiencies in medical records

Age
From **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method in this study was done by block randomization method in Excel software. So that after entering 80 samples (total number of people), the volume of group A was forty and the volume of group B was 40. Then, using the Random function tool in Excel software, the random number and random group of each sample were determined. The data evaluator is unaware of the random group of each sample.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: Participants assume that all participants have received the intervention and are unaware of the other group. Outcome Assessor: the radiographic evaluation, fracture classification, reduction, fixation quality and union process during the study will be reviewed by 2 blinded observer surgeon using digital radiographs on a computer Without knowing each

person's group. In case of disagreement, the results will be reviewed blinded by a third surgeon. Data Analyzer: Without knowing the details of the control and experimental group, analyzed the data in 2 separate groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

No 98 and 4; Mohandes alley; Adibi street; Shariati street

City

Tehran

Province

Tehran

Postal code

1613636681

Approval date

2020-06-07, 1399/03/18

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.200

Health conditions studied

1

Description of health condition studied

Intertrochanteric Fractures

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fracture healing time

Timepoint

Imaging at 2 and 4 weeks after surgery, then every 4 weeks until the fracture heals after taking teriparatide

Method of measurement

Radiological evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergoing gamma nail surgery also receive Teriparatide(Cinnopar-Cinnagen company) 20 micrograms subcutaneously per day from the day of discharge for 3 months in addition to calcium supplementation (600mg daily for 3 months).

Category

Treatment - Drugs

2

Description

Control group: Patients who undergo surgery with the Gamma nail technique and receive only calcium supplementation(600mg daily for 3 months).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Mostafa Hassannejad

Street address

Emam Hossein Hospital, Madani street

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

Info@ehmc.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

No 98 and 4; Mohandes alley; Adibi street; Shariati street

City

Tehran

Province

Tehran

Postal code

1613636681

Phone

+98 21 8602 5210

Email

Behnamtarinn@gmail.com

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

Mohammad Mehdi Omidian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

No 98 and 4; Mohandes alley; Adibi street; Shariati street

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Title and more details about the data/document

I would like to share the data file after deleting the confidential information. The total results of radiological evaluation of patients in 2 study groups will be presented.

When the data will become available and for how long

Start access 1 year after printing results

To whom data/document is available

physicians

Under which criteria data/document could be used

It is unknown at this time

From where data/document is obtainable

Send email to behnamtarinn@gmail.com

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

unknown

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Omidian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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