

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### The frequency of mortality and morbidity following intertrochanteric fracture in patients over 60 years of age who received vitamin D compared to controls

#### Protocol summary

##### Study aim

The aim of this study was to compare patients in intervention and control groups regarding changes in serum vitamin D levels, complications and mortality after intertrochanteric fracture

##### Design

In this clinical trial, people who refer to the orthopedic ward of Besat Hospital in Hamadan with a hip fracture first patients' vitamin D levels will be measured. If the serum level of vitamin D is less than 20 ng / ml, patients will be randomly assigned to one of the intervention or control groups using a sealed envelope.

##### Settings and conduct

A non-blinding study will be performed on patients over 60 years of age with intertrochanteric hip fracture referred to Besat Hospital in Hamadan.

##### Participants/Inclusion and exclusion criteria

Participants in the study included patients over 60 years of age with intertrochanteric fractures of the hip joint with a serum vitamin D level less than 20 ng / ml. Patients with a history of previous pelvic fractures will be excluded from the study.

##### Intervention groups

Intervention group will receive 600,000 Units vitamin D supplement of muscle injection. The control group is not given vitamin D supplements.

##### Main outcome variables

The main outcome of the study will be effects of vitamin D supplementation on serum vitamin D levels, complications and mortality following intertrochanteric fracture of the hip joint.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151123025202N14**

Registration date: **2021-02-13, 1399/11/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-13, 1399/11/25**

Update count: **0**

##### Registration date

2021-02-13, 1399/11/25

##### Registrant information

###### Name

Abbas Moradi

###### Name of organization / entity

Hamedan University of Medical Of Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0097

###### Email address

a.moradi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-20, 1399/11/01

##### Expected recruitment end date

2022-06-22, 1401/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The frequency of mortality and morbidity following intertrochanteric fracture in patients over 60 years of

age who received vitamin D compared to controls

### Public title

The effect of vitamin D on complications and mortality of intertrochanteric fracture hip fracture in over 60 years patients

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age over 60 years Intertrochanteric fracture Serum level of vitamin D less than 20 ng / ml

#### Exclusion criteria:

History of previous pelvic fractures

### Age

From **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

We made 80 cards and write letter I on 50 for Intervention and on the other 50 letter C for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and will be opened, based on selected letter I or C patients will be assigned to intervention or control group.

### 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

Ethics committee of Hamadan University of Medical Science

##### Street address

shahid fahmideh avenue

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838697

### Approval date

2021-01-16, 1399/10/27

### Ethics committee reference number

IR.UMSHA.REC.1399.868

## Health conditions studied

### 1

#### Description of health condition studied

Intertrochanteric fracture

#### ICD-10 code

S72.14

#### ICD-10 code description

Intertrochanteric fracture of femur

## Primary outcomes

### 1

#### Description

Changes in serum levels of vitamin D.

#### Timepoint

One year after the fracture

#### Method of measurement

Blood serum test

## Secondary outcomes

### 1

#### Description

Complications following a fracture

#### Timepoint

Within a year after the fracture

#### Method of measurement

Physical examination

### 2

#### Description

mortality incidence after fracture

#### Timepoint

Within a year after the fracture

#### Method of measurement

Phone follow up

## Intervention groups

### 1

#### Description

Intervention group: Receiving a vitamin D supplement in a vial of 600,000 units of single-dose intramuscular injection

#### Category

Prevention

2

**Description**

Control group: They will receive routine postoperative care without injecting vitamin D.

**Category**

Prevention

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Besat Hospital

**Full name of responsible person**

dr Morteza Majidi

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

dr Saeid Bashirian

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Shahid Fahmide Ave

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vc\_research@umsha.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Abbas Moradi

**Position**

Coach

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

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Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Morteza Majidi

**Position**

Associated professor pf orthpedia

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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## Person responsible for updating data

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**Other areas of specialty/work**

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**Postal code**

6517838736

**Phone**

## 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

No more information

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available