

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Street address

Shahid Beheshti Blvd

City

Hamadan

Province

Hamadan

Postal code

6514845411

Phone

+98 81 3264 0030

Fax

+98 81 3265 1515

Email

Besat@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

dr Saeid Bashirian

Street address

Shahid Fahmide Ave

City

Hamedan

Province

Hamadan

Postal code

6517838677

Phone

+98 81 3838 0717

Fax

+98 81 3838 0130

Email

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

Street address

shahid fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3838 0097

Fax

+98 81 3838 0208

Email

a.moradi@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

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

Street address

Shahid Beheshti Blv

City

Hamadan

Province

Hamadan

Postal code

6514845411

Phone

+98 81 3838 0092

Fax

Email

majidi57@yahoo.com

Web page address

+98 81 3838 0097

Fax

+98 81 3838 0208

Email

a.moradi@umsha.ac.ir

Person responsible for updating data

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

Street address

Hamedan shahid fahmideh street medicine school

City

Hamadan

Province

Hamadan

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