

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Effect of low dose pamidronate in the treatment of thalassemia-induced osteoporosis

#### Protocol summary

##### Study aim

The present study designed to evaluate the impact of pamidronate on the BMD of major beta-thalassemia patients to improve the quality of life in these individuals.

##### Design

Clinical trial without control group. With single group. Not blind .No instance of randomization. 20 patients

##### Settings and conduct

Transfusion-dependent major beta-thalassemia patients under follow-up and treatment in haematology-clinic will be enrolled in study .Bone mineral density of the lumbar vertebra and hip joint using dual X-Ray absorptiometry will be done. Z scores values <-2.5 will be treated with Pamidronate in the monthly dosages of 1 mg/kg over six months, intravenously. Bone mineral density will be measured again after 6 months.

##### Participants/Inclusion and exclusion criteria

Z-score < -2.5 in BMD, Ferritin level>1000 mg/dl, upwards of 10 blood infusions, >100cc/kg of blood infusion per year, and normal creatinine level and blood counts Exclusion: included the positive history of bone-related disorders, leukemia or neoplastic disorders, gastrointestinal disorders, and chronic inflammatory diseases.

##### Intervention groups

Transfusion-dependent major beta-thalassemia patients under follow-up and treatment in haematology-clinic will be enrolled in study .Bone mineral density of the lumbar vertebra and hip joint using dual X-Ray absorptiometry will be done. Z scores values <-2.5 will be treated with Pamidronate in the monthly dosages of 1 mg/kg over six months, intravenously. Bone mineral density will be measured again after 6 months.

##### Main outcome variables

bone mineral densitometry

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211008052698N1**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **retrospective**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

##### Registration date

2021-10-29, 1400/08/07

##### Registrant information

##### Name

Farid Ghazizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3224 1967

##### Email address

ghazizadeh.f@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-16, 1400/05/25

##### Expected recruitment end date

2021-09-06, 1400/06/15

##### Actual recruitment start date

2020-09-15, 1399/06/25

##### Actual recruitment end date

2021-09-16, 1400/06/25

##### Trial completion date

2021-10-17, 1400/07/25

##### Scientific title

Effect of low dose pamidronate in the treatment of thalassemia-induced osteoporosis

## Public title

Treatment of thalassemia-induced osteoporosis with pamidronate

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Z-score < -2.5 in Bone Mineral Densitometry Ferritin level>1000 mg/dl More than 10 blood infusions or More than 100 cc/kg of blood infusion per year Normal creatinine level Normal blood counts

### Exclusion criteria:

The positive history of bone-related disorders Leukemia or Neoplastic disorders Gastrointestinal disorders Chronic inflammatory diseases

## Age

No age limit

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 20

Actual sample size reached: 20

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of urmia University of Medical Sciences

##### Street address

Emergency Alley,Resalat Boulevard,urmia city

##### City

urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

## Approval date

2015-09-21, 1394/06/30

## Ethics committee reference number

IR.USBMSU.MSP.REC.13946.133900

## Health conditions studied

### 1

#### Description of health condition studied

Thalassemia

#### ICD-10 code

D56.1

#### ICD-10 code description

Beta thalassemia

## Primary outcomes

### 1

#### Description

Bone mineral densitometry

#### Timepoint

Baseline , Six month later

#### Method of measurement

Dual X-Ray absorptiometry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Pamidronate , intravenously in the monthly dosages of 1 mg/kg over six month

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

بیمارستان مطهری

##### Full name of responsible person

Farid Ghazizadeh

##### Street address

Shahid Motahari Hospital,Ayatollah Kashani St,Urmia

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

2344432987

##### Phone

+98 44 3224 1967

##### Email

beigzadeh.silvana@gmail.com

**Web page address**

https://motahari.umsu.ac.ir/

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Iraj Mohebi

**Street address**

Shahid Motahari Hospital, Ayatollah Kashani St, Urmia

**City**

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**Province**

West Azarbaijan

**Postal code**

3847233987

**Phone**

+98 44 3224 1967

**Email**

gazizadef@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Farid Ghazizadeh

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

**Street address**

Jam jam

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**Province**

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**Postal code**

5716656692

**Phone**

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**Fax****Email**

ghazizadeh.f@umsu.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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**

Not applicable

### **Title and more details about the data/document**

all of study information will be shared after changing to an unrecognizable format

### **When the data will become available and for how long**

data will be available 6 months after results submission

### **To whom data/document is available**

every body

### **Under which criteria data/document could be used**

free access

### **From where data/document is obtainable**

contact with corresponding author

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

3 to 4 months after receiving request

### **Comments**