

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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, >100 cc/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		2015-09-21, 1394/06/30	
Public title Treatment of thalassemia-induced osteoporosis with pamidronate		Ethics committee reference number IR.USBMSU.MSP.REC.13946.133900	
Purpose Treatment		Health conditions studied	
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		1 Description of health condition studied Thalassemia ICD-10 code D56.1 ICD-10 code description Beta thalassemia	
Age No age limit		Primary outcomes	
Gender Both		1 Description Bone mineral densitometry	
Phase 2		Timepoint Baseline , Six month later	
Groups that have been masked No information		Method of measurement Dual X-Ray absorptiometry	
Sample size Target sample size: 20 Actual sample size reached: 20		Secondary outcomes empty	
Randomization (investigator's opinion) N/A		Intervention groups	
Randomization description		1 Description Intervention group: Pamidronate , intravenously in the monthly dosages of 1 mg/kg over six month	
Blinding (investigator's opinion) Not blinded		Category Treatment - Drugs	
Blinding description		Recruitment centers	
Placebo Not used		1 Recruitment center	
Assignment Single		Name of recruitment center بیمارستان مطهری	
Other design features		Full name of responsible person Farid Ghazizadeh	
Secondary Ids empty		Street address Shahid Motahari Hospital,Ayatollah Kashani St,Urmia	
Ethics committees		City Urmia	
1 Ethics committee		Province West Azarbaijan	
Name of ethics committee Ethics committee of urmia University of Medical Sciences		Postal code 2344432987	
Street address Emergency Alley,Resalat Boulevard,urmia city		Phone +98 44 3224 1967	
City urmia		Email beigzadeh.silvana@gmail.com	
Province West Azarbaijan			
Postal code 5714783734			
Approval date			

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
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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
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Person responsible for updating data

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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