# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Evaluation of intravenous pamidronate & oral alendronate on bone marrow density in patients with major and intermedia thalassemia

## Protocol summary

**Summary**

the Aim of this study is to Evaluate the intravenous pamidronate and oral alendronate on bone marrow density in patients with major and intermedia thalassemia in Amirkabir hospital. this study is clinical trials in patients with major and inter media thalassemia with age more than 10 years referred to Amir kabir hospital.We will divide patients into two groups(each group 20 person).We evaluate bone density of the spine and neck of the femur in patients.We prescribe 70 milligram Alendronate once a week in A group. We prescribe 0.5 milligram per kilogram of Pamidronate IV in day for three days in B group. If the calcium is above 8 milligram in milliliter , the drug is injected into the patient.We follow up patients for one years.We evaluate bone density of the spine and neck of the femur and record the improvement of patient's clinical symptoms .Inclusion criteria: patients with major and inter media thalassemia with age more than 10 years referred to Amir kabir hospital. Exclusion criteria: Gastrointestinal intolerance for oral medication; having allergic drug reaction ; heart failure; liver failure; hypoparathyroidism

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017070420258N51**
Registration date: **2017-07-16, 1396/04/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2017-07-16, 1396/04/25

**Registrant information**

**Name**

Fariba Farokhi

**Name of organization / entity**

Arak University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 86 3222 2003

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor and Research,Arak University of Medical Sciences

**Expected recruitment start date**

2017-02-08, 1395/11/20

**Expected recruitment end date**

2020-02-09, 1398/11/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of intravenous pamidronate & oral alendronate on bone marrow density in patients with major and intermedia thalassemia

**Public title**

Evaluation of intravenous pamidronate & oral alendronate on bone marrow density in patients with major and intermedia thalassemia

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: patients with major and inter media thalassemia ,age more than 10 years referred to Amir kabir hospital Exclusion criteria: Gastrointestinal

intolerance for oral medication; having an allergic drug; heart failure; liver failure; hypoparathyroidism

**Age**
From **10 years** old to **139 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double 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 Arak University Of Medical Sciences

**Street address**
Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

**City**
Arak

**Postal code**
38149578558

**Approval date**
2017-02-06, 1395/11/18

**Ethics committee reference number**
IR.ARAKMU.REC.1395.383

## Health conditions studied

### 1

**Description of health condition studied**
major and inter media thalassemia

**ICD-10 code**
D56.1

**ICD-10 code description**
Beta thalassaemia

## Primary outcomes

### 1

**Description**
Spinal bone density and femoral neck

**Timepoint**
End of one years

**Method of measurement**
X-ray photography

### 2

**Description**
Improve the status of clinical symptoms

**Timepoint**
End of one years

**Method of measurement**
clinical observation

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: We prescribe 70 milligram Alendronate once a week in A group.

**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: We prescribe 0.5 milligram in kilogram of Pamidronate IV in day for three day in B group.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Amirkabir Hospital

**Full name of responsible person**
Dr Fatahibayat

**Street address**
Amirkabir hospital, Parastar square, Arak

**City**
Arak

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Vice chancellor for research, Arak University of

Medical Sciences

**Full name of responsible person**
Dr Mohammad Rafiee

**Street address**
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

**City**
Arak

**Grant name**
-

**Grant code / Reference number**
-

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

**Title of funding source**
Vice chancellor for research, Arak University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
*empty*

**Domestic or foreign origin**
*empty*

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Arak University of Medical Sciences

**Full name of responsible person**
Dr Aziz Eghbali

**Position**
Faculty Member

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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Mahmod Nahremiany

**Position**
Medicine Student

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*

**Study Protocol**
*empty*

**Statistical Analysis Plan**
*empty*

**Informed Consent Form**
*empty*

**Clinical Study Report**
*empty*

**Analytic Code**
*empty*

**Data Dictionary**
*empty*