# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of Bisphosphonate diet with and without testosterone on bone density parameters in male patients with major thalassemia

## Protocol summary

**Study aim**

Determining the effect of Bisphosphonate with and without Testosterone on bone density parameters in male patients with Thalassemia major

**Design**

A Quasi experimental study with parallel, single blinded groups on 40 patients with major Thalassemia.

**Settings and conduct**

This study conducted in Aliasghar Children's Hospital. Patients with major Thalassemia and eligible divided to four groups. In the first Intervention group, patients with hypogonadism took Alendronate and testosterone, In the second Intervention group, Patients with hypogonadism took testosterone, In the first control group, patients with hypogonadism who did not receive any treatment, In the Second control group,patients without hypogonadism took Alendronate. In this study, the doctor did not know the type of drug received.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Male patients with major thalassemia and older than 13.5 years, Patients with hypogonadism and without hypogonadism. Exclusion criteria: Patients with abnormal levels of liver enzymes, Patients with abnormal levels of thyroid function hormones and diabetes, and Patients with a bone density greater than -5.2.

**Intervention groups**

In the first Intervention group, patients with hypogonadism took Alendronate and testosterone, In the second Intervention group, Patients with hypogonadism took testosterone, In the first control group, patients with hypogonadism who did not receive any treatment, In the Second control group,patients without hypogonadism took Alendronate.

**Main outcome variables**

Bone density

## General information

**Reason for update**

Unfortunately, we did not reach the desired sample size, and following that because random allocation was not ethical the design of the study and the number of subjects were changed

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201110049334N2**
Registration date: **2022-05-14, 1401/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-05, 1402/05/14**
Update count: **1**

**Registration date**

2022-05-14, 1401/02/24

**Registrant information**

**Name**

Davood Amirkashani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2304 6253

**Email address**

amirkashani.d@iums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-12-31, 1401/10/10

**Expected recruitment end date**

2022-12-31, 1401/10/10

**Actual recruitment start date**

2021-12-31, 1400/10/10

**Actual recruitment end date**

2022-12-31, 1401/10/10

**Trial completion date**
2022-12-31, 1401/10/10

**Scientific title**
The effect of Bisphosphonate diet with and without testosterone on bone density parameters in male patients with major thalassemia

**Public title**
The effect of Bisphosphonate on bone density in patients with major thalassemia

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients Consent to participate in the study Male patients with major thalassemia and older than 13.5 years Patients with hypogonadism (based on blood testosterone, LH and FSH levels) and without hypogonadism No concomitant underlying disease (including thyroid disease, parathyroid disease, kidney and liver disease and diabetes)

**Exclusion criteria:**
Patients with abnormal level of liver enzymes (AST and ALT) Patients with renal disorder Patients with abnormal levels of calcium, blood phosphorus and vitamin D3 Patients with abnormal levels of thyroid function hormones and diabetes Patients with abnormal levels of PTH and ALP Patients with bone density greater than -5.2 Do not take the drug by the patient until the end of the study

**Age**
From **14 years** old

**Gender**
Male

**Phase**
3

**Groups that have been masked**

- Care provider
- Investigator

**Sample size**
Target sample size: **40**
Actual sample size reached: **38**

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
This study is single-blinded. Only the doctor does not know the type of medicine received Method of blinding the doctor: The sealed enveloped medicine created is given to a researcher who does not interfere in choosing the type of medicine. After enrolling the subjects and collecting their baseline information by the doctor, the subjects go to the researcher to get the medicine, and the researcher will give one of the envelopes to the patients, and then the researcher then keeps a form that identifies what medication each patient has taken.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics committee of Iran University of Medical Sciences

**Street address**
Hemmat Highway, Next to the Milad Tower

**City**
Tehran

**Province**
Tehran

**Postal code**
1449614535

**Approval date**
2021-12-29, 1400/10/08

**Ethics committee reference number**
IR.IUMS.FMD.REC.1400.557

## Health conditions studied

**1**

**Description of health condition studied**
major thalassemia

**ICD-10 code**
D56.1

**ICD-10 code description**
Beta thalassemia

## Primary outcomes

**1**

**Description**
Bone density

**Timepoint**
At the beginning of the study and one year after the intervention

**Method of measurement**
Bone mineral density (BMD) test by DEXA method

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1: In this group, patients with

hypogonadism took Bisphosphonate (Alendronate, manufactured by Alborz Daro Company, Iran) for one year and one tablet at a dose of 70 mg per week,and testosterone (Testosterone Enanthate, manufactured by Iran Hormone, Iran) for one year at a dose of 250 mg per 3 to 4 weeks by injection.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group2: Patients with hypogonadism take testosterone (Testosterone Enanthate, manufactured by Iran Hormone, Iran) for one year at a dose of 250 mg per 3 to 4 weeks by injection.

**Category**

Treatment - Drugs

**3**

**Description**

Control group 1: Patients with hypogonadism who did not receive any treatment

**Category**

Treatment - Drugs

**4**

**Description**

Control group2: patients without hypogonadism took Bisphosphonate (Alendronate, manufactured by Alborz Daro Company, Iran) for one year and one tablet at a dose of 70 mg per week,and testosterone (Testosterone Enanthate, manufactured by Iran Hormone, Iran) for one year at a dose of 250 mg per 3 to 4 weeks by injection.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Aliasghar Children's Hospital
**Full name of responsible person**
Davod Amirkashani
**Street address**
No.193, Zafar St, Modares Highway.
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Tehran
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**Postal code**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Hosein Keivani
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**Phone**
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keivani.h@iums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Iran 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**
Iran University of Medical Sciences
**Full name of responsible person**
Davod Amirkashani
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Davod Amirkashani

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

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**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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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**

Undecided - It is not yet known if there will be 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**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

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

All data can be shared after subjects are not identified

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

Starting after 2023

**To whom data/document is available**

This is available for people working in academic institutions

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

There is no limitation

**From where data/document is obtainable**

Applicants should apply for the documents or data files only via the email of the main researcher (amirkashani.d@ius.ac.ir)

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

The following should be included in the requested e-mail first name and last name Organizational affiliation Commitment to copyright Reason for request Data usage After approval of the main researcher and the consent of the research members, the data are sent. The final decision will be emailed within two weeks.

**Comments**