

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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Phone

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Email

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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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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

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 updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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@iums.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