

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

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Iran (Islamic Republic of)

Phone

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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 squire, 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
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 Complex, Basij square, Sardasht, Arak
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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
 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
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 Faculty Member
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Person responsible for scientific inquiries

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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