Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of the effect of oral amlodipine on cardiac and liver iron load and echocardiographic indices in patients with beta-thalassemia major

Protocol summary

Study aim

The primary aim of this study is to evaluate the effect of oral amlodipine on cardiac and hepatic iron load in patients with major thalassemia.

Design

This is a phase 3, randomized, parallel, triple-blind, multicenter clinical trial with a placebo control. Fifty patients will be randomly assigned 1:1 using permuted blocks via SealedEnvelope.com, and study medication will be packaged with coded randomization.

Settings and conduct

Eligible patients with major thalassemia and cardiac iron overload will be enrolled and randomly assigned to amlodipine or placebo using permuted blocks. The investigator, participant, and Data Safety Monitoring Committee will remain blinded. Cardiac iron load will be measured by MRI-T2* at baseline and after 12 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with major thalassemia, aged ≥8 years, with significant cardiac iron overload Exclusion criteria: known allergy to amlodipine, refusal to take the study medication, or inability to follow study procedures

Intervention groups

Intervention group: participants will receive 5 mg oral amlodipine daily for 12 months, continuing their usual iron-chelation regimen Control group: participants will receive a placebo identical in appearance for 12 months, with their iron-chelation regimen unchanged

Main outcome variables

Cardiac iron deposition, hepatic iron deposition, left ventricular cardiac output index, left ventricular end-diastolic and end-systolic volumes, early (E) and late (A) diastolic filling velocities and their ratio (E/A), mitral annular velocity (e'), and serum ferritin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250421065432N1**
Registration date: **2026-02-17, 1404/11/28**
Registration timing: **prospective**

Last update: **2026-02-17, 1404/11/28**
Update count: **0**

Registration date

2026-02-17, 1404/11/28

Registrant information

Name

Alireza Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3362 2885

Email address

dralirezazamani72@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigation of the effect of oral amlodipine on cardiac and liver iron load and echocardiographic indices in patients with beta-thalassemia major

Public title
Oral Amlodipine and Cardiac Iron load in Beta-Thalassemia Major

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with β-thalassemia major ≥ 8 years old
Increased myocardial iron overload

Exclusion criteria:
Known hypersensitivity or allergy to amlodipine
Unwillingness to take the study medication Unwillingness to participate in the study Inability or unwillingness to follow study instructions (poor compliance)

Age
From **8 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
This study will be a randomized, parallel-group, double-blind, placebo-controlled, multicenter clinical trial. Based on the determined sample size, 50 patients will be allocated in a 1:1 ratio to either the intervention or control group. Randomization will be performed using permuted block randomization with a block size of 4 to ensure balanced allocation between the groups. Each patient will be considered an independent unit. The randomization sequence will be generated using the online statistical service sealedenvelope.com. To ensure allocation concealment, the sequence will be placed in sequentially numbered, sealed, opaque envelopes. The enrolling investigators will be blinded to group assignment, and an envelope will only be opened after a patient is formally enrolled.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The active drug and placebo will be manufactured as tablets identical in appearance, size, color, odor, and packaging by a pharmacotherapy specialist at Mofid Children's Hospital. Medication packages will be labeled only with a unique patient identification code and stored in the central research pharmacy. After eligibility is confirmed and informed consent is obtained, each enrolled patient will be sequentially assigned an identification code. The pharmacy will then dispense the corresponding monthly medication package. All paraclinical assessments will be performed by trained technicians and physicians who are blinded to the patient's treatment assignment. Following the completion of the 12-month treatment period and data collection, a blinded statistician will conduct the preliminary analysis using coded groups (A and B). After review and approval by the monitoring committee, the sealed envelopes containing the allocation codes will be opened by an independent, blinded party (the research manager) to reveal the actual group assignments for the final analysis. Finally, participants and research staff will be asked to guess the assigned treatment group to assess the success of blinding.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, School of Medicine, Shahid Beheshti University of Medical Sciences

Street address
Ethics Committee, School of Medicine, Shahid Beheshti University of Medical Sciences, Shahid Chamran Highway, Yemen St., Shahid Arabi St., Next to Ayatollah Taleghani Hospital, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
193954719

Approval date
2024-10-08, 1403/07/17

Ethics committee reference number
IR.SBMU.MSP.REC.1403.406

Health conditions studied

1

Description of health condition studied
Beta-thalassemia major

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia major

2

Description of health condition studied

Myocardial siderosis

ICD-10 code

I51.9

ICD-10 code description

Heart disease, unspecified

3

Description of health condition studied

Hepatic iron load

ICD-10 code

K76.89

ICD-10 code description

Other specified diseases of liver

4

Description of health condition studied

Ferritin serum level

ICD-10 code

R79.89

ICD-10 code description

Other specified abnormal findings of blood chemistry

Primary outcomes

1

Description

Cardiac iron measured by MRI-T2*

Timepoint

Myocardial iron deposition is measured at the baseline (before the intervention) and 12 months after the administration of amlodipine.

Method of measurement

cardiac MRI (T2*- MRI)

Secondary outcomes

1

Description

Left ventricular ejection fraction measured by echocardiography

Timepoint

Cardiac indices are measured at the baseline (before the intervention) and 12 months after the administration of amlodipine.

Method of measurement

echocardiography

2

Description

Hepatic iron load measured by MRI

Timepoint

Hepatic iron deposition is measured at the baseline (before the intervention) and 12 months after the administration of amlodipine.

Method of measurement

liver MRI

3

Description

Serum ferritin level

Timepoint

Serum ferritin level is measured at the baseline (before the intervention) and 12 months after the administration of amlodipine.

Method of measurement

ELISA

4

Description

Left ventricular end-diastolic volume measured by echocardiography

Timepoint

Cardiac indices are measured at the baseline (before the intervention) and 12 months after the administration of amlodipine.

Method of measurement

echocardiography

5

Description

Left ventricular end-systolic volume measured by echocardiography

Timepoint

Cardiac indices are measured at the baseline (before the intervention) and 12 months after the administration of amlodipine.

Method of measurement

echocardiography

6

Description

Early (E) to late (A) ventricular filling velocities (E/A ratio) measured by echocardiography

Timepoint

Cardiac indices are measured at the baseline (before the intervention) and 12 months after the administration of amlodipine.

Method of measurement

echocardiography

7

Description

Mitral annular velocity (e') measured by echocardiography

Timepoint

Cardiac indices are measured at the baseline (before the intervention) and 12 months after the administration of amlodipine.

Method of measurement

echocardiography

Intervention groups

1

Description
Intervention group:Patients in the intervention group will receive one oral tablet of amlodipine daily for a period of 12 months. The dosage will be 5 mg for patients weighing ≥30 kg and 2.5 mg for patients weighing <30 kg. The tablets will be manufactured by Rooz Darou Pharmaceutical Company and administered orally. The patients' standard iron chelation regimen will be continued without any modification.

Category
Treatment - Drugs

2

Description
Control group:Patients in the control group will receive one oral placebo tablet daily for a period of 12 months. The placebo will be identical to amlodipine in terms of appearance, color, packaging, and taste, with the only difference being the absence of the active ingredient. The tablets will be manufactured by Rooz Darou Pharmaceutical Company and administered orally. The patients' standard iron chelation regimen will be continued without any modification.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Childrens Hospital
Full name of responsible person
Alireza Zamani
Street address
Mofid Children's Hospital, Shariati Street, above Hosseiniyeh Ershad, before Mirdamad, Tehran, Iran
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2

Recruitment center
Name of recruitment center
Shohada-e-Tajrish Hospital
Full name of responsible person
Alireza Zamani
Street address
Shohada-ye Tajrish Hospital, Darband Street, Ghods Square, Tajrish, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Shahid Chamran Highway, Yemen St., Shahid Arabi St., Next to Ayatollah Taleghani Hospital, Tehran, Iran
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Postal code
19395 4719
Phone
+98 21 8670 5503
Email
info@sbmu.ac.ir
Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Samin Alavi
Position
Professor

Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Pediatric Hematology and Oncology Research Center, Mofid Children's Hospital, Shariati Street, Tehran, Iran
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
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Subspecialty Fellow
Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to privacy, we do not plan for sharing the other data.
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data of the subjects will be provided considering their private data.
When the data will become available and for how long
Access period start: 6 months after results publication
To whom data/document is available
The data will be provided to all readers who ask for it.
Under which criteria data/document could be used
The data will be provided through sending email to the corresponding author.
From where data/document is obtainable
The request for data could be sent to: saminalavi@hotmail.com
What processes are involved for a request to access data/document
At least six months after results publication, data will be provided to the requester by e-mail upon submission of a request and explanation of its purpose, within less than one month.
Comments