Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of the effect of amilodipine on heart function and cardiac iron deposition in β-thalassemia patients: A randomized double blind crosss-over study

Protocol summary

Study aim
Evaluation of the effect of amilodipine on heart function and cardiac iron deposition in β-thalassemia patients
Design
Randomized, double blind cross over clinical trial
Settings and conduct
The study will be conducted in Bouali Sina Educational Hospital in Sari. Patients will receive amlodipine 5 mg daily or placebo for 6 months. The order of intervention (first amlodipine then placebo or vice versa) will be determined randomly. The wash out period will be 2 weeks. Measurement of ferritin levels and MRI T2 evaluation will be performed at the start of the study, on the 6th and 12th months. C
Participants/Inclusion and exclusion criteria
Inclusion criteria : 1. beta-thalassemia patients with moderate to severe heart sediment (MRI based on a less than 15 milliseconds) 2. Age over 18 years 3. Conscious written consent Exclusion criteria: 1. Other medicines for calcium blocker (verapamil-diltiazem-cartidilol) 2. Continuous hypotension due to heart failure severity 3. Aortic valve stenosis 4. Sinoatrial node disease 5. Heart failure
Intervention groups
Intervention group: amlodipine tablets 5 mg daily for 6 months Control group: Amlodipine placebo daily for 6 months
Main outcome variables
Cardiac MRI T2

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090613002027N15**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **retrospective**

Last update: **2019-08-26, 1398/06/04**
Update count: **0**
Registration date
2019-08-26, 1398/06/04

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-01-10, 1397/10/20
Expected recruitment end date
2019-07-11, 1398/04/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of amilodipine on heart function and cardiac iron deposition in β-thalassemia patients: A randomized double blind crosss-over study

Public title

Effect of amilodipine on heart function and cardiac iron deposition in β-thalassemia patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Beta-thalassemia patients with moderate to severe heart sediment (MRI based on a less than 15 milliseconds) Age over 18 years Written informed consent

Exclusion criteria:
Use of other calcium channel blockers (verapamil-diltiazem-carvedilol) Continuous hypotension due to heart failure severity Aortic valve stenosis Sinoatrial node diseas Heart failure

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified randomization will be performed for patients based on MRI before enrollment in the study [MRI T2 of 10 to 15 milliseconds (moderate iron deposition in the heart) and MRI T2 of less than 10 milliseconds (severe iron deposition in the heart). Whether the patient receives first Amlodipine then Placebo or first Placebo then Amlodipine will be determined by block randomization with 4 cases in each block. Drugs and placebo will be put in containers with the same shape. The patients and the physician will not be aware of the group they are assigned to.

Blinding (investigator's opinion)
Double blinded

Blinding description
A separate 5-digit code obtained from the computer will be assigned to each patient.The intervention, including the drug or placebo, will be placed in identical containers, and the senior researcher will insert the code on the containers. The researcher and patient will not be aware of the type of intervention received.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of mazandaran university of medical sciences

Street address
School of Pharmacy of Mazandaran University of Medical Sciences, Payambar azam University Complex, Farah Abad road, Khazar Square

City
sari

Province
Mazandaran

Postal code
861-48175

Approval date
2019-01-06, 1397/10/16

Ethics committee reference number
IR.MAZUMS.REC.1398.280

Health conditions studied

1

Description of health condition studied
β-thalassemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Cardiac MRI T2

Timepoint
Baseline, month 6 and month 12

Method of measurement
Performing MRI T2

2

Description
Left Ventricular End Diastolic Diameter (LVEDD)

Timepoint
Baseline, month 6 and month 12

Method of measurement
Echoardiography

3

Description
Left Ventricular End Systolic Diameter (LVESD)

Timepoint
Baseline, month 6 and month 12

Method of measurement
Ecocardiography

Secondary outcomes

1

Description
Ferritin
Timepoint
Baseline, month 6 and month 12
Method of measurement
Kit of ferritin assay

Intervention groups

1

Description
Intervention group: amlodipine tablets 5 mg daily for 6 months
Category
Treatment - Drugs

2

Description
Control group: Amlodipine placebo daily for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
BooAli Sina Educational Hospital, Sari
Full name of responsible person
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Sponsors / Funding sources

1

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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
Sari 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
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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
Confidentiality of patients data
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available