# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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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Ebrahim Salehifar
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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**
ابراهیم صالحی فر
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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

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## Person responsible for updating data

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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