Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of amlodipine on oxidative stress markers and serum ferritin level in β-thalassemia patients undergoing iron chelation therapy: A randomized double-blind Cross-Over study

Protocol summary

Study aim
Evaluation of the effect of amlodipine on oxidative stress markers and serum ferritin level in β-thalassemia patients undergoing iron chelation therapy

Design
A randomized, double blind cross over clinical trial

Settings and conduct
This randomizes double blind cross over clinical trial will be conducted in Bouali Sina Educational Hospital in Sari.

Participants/Inclusion and exclusion criteria
Inclusion criteria : 1. beta-thalassemia patients with moderate to severe heart iron overload (MRI T2 less than 15 milliseconds) 2. Age over 18 years 3. Informed written consent Exclusion criteria: 1. Use of other calcium channel blocker (verapamil-diltiazem-carvedilol) 2. Continuous hypotension due to heart failure 3. Aortic valve stenosis 4. Sinoatrial node disease 5. Heart failure

Intervention groups
Beta-thalassemia patients with moderate to severe iron overload will be assigned into two groups including first amlodipine then placebo or first placebo then amlodipine.

Main outcome variables
Primary outcomes are oxidative stress markers (malondialdehyde, protein carbonyl and total antioxidant) and secondary outcome is ferritin level.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090613002027N16**
Registration date: **2019-09-17, 1398/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-17, 1398/06/26**
Update count: **0**

Registration date
2019-09-17, 1398/06/26

Registrant information

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Ebrahim Salehifar

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-09, 1397/10/19

Expected recruitment end date
2019-12-10, 1398/09/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of amlodipine on oxidative stress markers and serum ferritin level in β-thalassemia patients undergoing iron chelation therapy: A randomized double-blind Cross-Over study

Public title
effect of amlodipine on oxidative stress markers and serum ferritin level in β-thalassemia patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Beta-thalassemia patients with moderate to severe heart sediment (based on MRI T2 less than 15 milliseconds) Age over 18 years Written informed consent
Exclusion criteria:
Other medicines for calcium blocker (verapamil-diltiazem-cartidilol) Continuous hypotension due to heart failure 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). Ŵhether the patient receives first Amlodipine then Placebo or first Placebo then Amlodipine will be determined by block randomization.
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 Committee of mazandaran University of Medical Sciences
Street address
Mazandaran University of Medical Scienses, kilometer 18 of Farah Abad road, Sari, Iran
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4816633131
Approval date
2019-01-06, 1397/10/16
Ethics committee reference number
IR.MAZUMS.REC.1398.281

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
Oxidative stress indices (malondialdehyde, carbonyl protein and total antioxidant)
Timepoint
Baseline, month 6 and month 12
Method of measurement
Laboratory analysis

Secondary outcomes

1

Description
Ferritin
Timepoint
Baseline, month 6 and month 12
Method of measurement
Laboratory analysis

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
Thalassemia Research Center
Full name of responsible person
Ebrahim Salehifar
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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?
Yes
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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Professor of Clinical Pharmacy
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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 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
Undecided - It is not yet known if there will be 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