

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Name

Ebrahim Salehifar

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1311 6546

Email address

esalehifar@mazums.ac.ir

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 diseases 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.

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 Sciences, kilometer 18 of Farah Abad road, Sari, Iran

City

sari

Province

Mazandaran

Postal code

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

Street address

Bu-Ali Sina Hospital, Blvd.Pasdaran, Sari, Iran

City

sari

Province

Mazandaran

Postal code

4816633131

Phone

Email

esalehifar@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

Street address

Research Deputy, Mazandaran university of medical Sciences, Moallem Square, Sari, Iran

City

sari

Province

Mazandaran

Postal code

861-48175

Phone

+98 11 3354 3241

Email

msaeedi@mazums.ac.ir

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

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Position

Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy of Mazandaran University of Medical Sciences, Payambar azam University Complex, Farah Abad road, Sari, Iran

City

sari

Province

Mazandaran

Postal code

861-48175

Phone

+98 11 3354 3241

Email

salehifare@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Position

Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar squar

City

sari

Province

Mazandaran

Postal code

861-48175

Phone

+98 11 3354 3241

Email

salehifare@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Position

Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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

Phone

+98 11 3354 3241

Email

salehifare@yahoo.com

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