Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The study of the effects of amlodipine addition to combination therapy of Deferiprone and Deferoxamine to reduce cardiac iron overload measurable with T2*MRI in thalassemic patients

Protocol summary

Study aim
The effect of adding amlodipine to combination therapy of desferal and deferiprone on reducing cardiac iron overload measurable by T2 * MRI

Design
This study is a randomized double-blind clinical trial. In this study, 30 patients with thalassemia major who are over 5 years old and have been receiving blood for at least 2 years on a regular basis were enrolled after informed consent. Patients will be randomly divided into two equal groups. In the intervention group, patients will receive amlodipine at a dose of 5 and 2.5 mg with chelator and in the control group will receive chelator only for one year.

Settings and conduct
This study is a randomized double blind clinical trial on all thalassemia major patients referred to Amir Kabir Hospital in Arak. And statistics experts who analyze the data are blind to the groups, and only the hematologist and interns in charge of the study are aware of the study groups.

Participants/Inclusion and exclusion criteria
In this study, 30 patients with thalassemia major who are over 5 years old and have been receiving blood for at least 2 years on a regular basis were enrolled after informed consent. Patients will be followed for amlodipine side effects. Patients with hepatic impairment, hepatitis B and C, HIV, chelation therapy changes during the last 6 months, heart failure (EF less than 30%), AV block, any inflammation and renal failure will be excluded.

Intervention groups
In the intervention group, patients will receive amlodipine at a dose of 5 and 2.5 mg with chelator and in the control group will receive chelator only for one year. After one week of treatment with amlodipine, the dose will increase to 5 mg.

Main outcome variables
Serum ferritin level; Iron overload in cardiac T2. * MRI

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190829044642N1**
Registration date: **2020-08-03, 1399/05/13**
Registration timing: **retrospective**

Last update: **2020-08-03, 1399/05/13**
Update count: **0**

Registration date
2020-08-03, 1399/05/13

Registrant information
Name
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Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-09-23, 1398/07/01
Expected recruitment end date
2019-11-22, 1398/09/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effects of amlodipine addition to combination therapy of Deferiprone and Deferoxamine to reduce cardiac iron overload measurable with T2*MRI in thalassemic patients

Public title

effects of amlodipine to reduce cardiac iron overload

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. All patients had informed consent to participate in the study. 2- All thalassemia major patients referring to Amir Kabir Hospital, Arak, over 5 years old. .3. All healthy children without any underlying hematologic or hereditary diseases except major thalassemia

Exclusion criteria:

All patients who did not have informed consent to participate and continue to participate in the study. All patients who will undergo a chelation therapy strategy during the 12 months of study due to changes. All patients with advanced heart failure or Ef less than 30% or AV block All patients with MRI contraindication All patients with liver disorders, hepatitis B and C, HIV, any inflammation and renal failure All patients who have complications with amlodipine include edema, hypotension, palpitations, etc

Age

From **5 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 30 patients with thalassemia major who are over 5 years old and have received blood regularly for at least 2 years are included in the study. To assign patients to two groups, the block randomization method with the size of four blocks was used. Thus, using online software, the randomization sequence was generated by the block method and remained with the epidemiologist and sought to diagnose and In the first group, 15 patients received amlodipine at a dose of 2.5-5 mg with a chelator, and in the second group, 15 patients received chelator. Will receive alone for one year.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind randomized clinical trial in Amir Kabir hospital in Arak in 1398 with easy sampling. In this study, 30 patients with major thalassemia who are over 5 years old and have been receiving blood for at least 2 years on a regular basis were enrolled after informed consent. Blindness Due to the double blindness of the study means that only the relevant expert in the study is aware of the study type and study groups, while the patients and the statistical experts responsible for analyzing the data are aware. Patients in charge are not aware of the study groups and only identify patients based on groups A and B and complete the checklists accordingly

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Shahid shirudi Ave., Alamolhoda St.

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Markazi

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3819693345

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.ARAKMU.REC.1397.357

Health conditions studied

1

Description of health condition studied

Major Thalasemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Cardiac iron overload

Timepoint

Will be measured at baseline and 12 months after treatment.

Method of measurement

T2*MRI

Secondary outcomes

1

Description

ferritin serum level

Timepoint

At baseline and 1, 6, 12 months after treatment

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Patients will receive amlodipine at a dose of 5 to 2.5 mg with chelator for one year. After one week of treatment with amlodipine, the dose will increase to 5 mg.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive only chelators for one year.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

Shima Vakilipour

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Shiroudi Ave., Alamolhoda St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

علیرضا کمالی

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Shima Vakilipour

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available