Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Amlodipine on reduce of iron overload in patients with major thalassemia above 7 years old

Protocol summary

Summary

Aim of this study is the effect of Amlodipine in reduce iron levels in patients with major Thalassemia who referred to Arak Amirkabir hospital. Inclusion criteria: Patients with major Thalassemia with regular blood transfusions; using iron chelating agents regularly; age above 7 years old. Exclusion criteria: Patients who changed their chelating agents during the last 6 months; renal and hepatic failure; cardiac output less than 35%; systolic blood pressure less than 90 millimeter Hg; patients with HIV and hepatitis B and C. We will measure complete blood count (CBC) and liver function test (LFT) and renal function test (BUN / Cr) and ferritin level and hepatitis serology B, C, HIV and echocardiography and T2*MRI of heart and liver and ejection fraction(EF) for all patients before study. We will divide patients to two groups. We prescribe chelating agent in control group and Amlodipine addition chelator agents in intervention group. If systolic blood pressure is above 90 millimeter Hg, We will prescribe 2.5 mg Amlodipine once daily for first week. If blood pressure is normal, We prescribe 5 mg Amlodipine once daily for12 months. We will measure ferritin levels 1 and 6 and 12 months after treatment. We will check blood pressure monthly. We will measure T2*MRI of heart and liver after 6 and 12 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080720715N2**
Registration date: **2017-03-27, 1396/01/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-27, 1396/01/07

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-05-27, 1394/03/06

Expected recruitment end date

2016-08-27, 1395/06/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Amlodipine on reduce of iron overload in patients with major thalassemia above 7 years old

Public title

Effect of Amlodipine on reduce of iron overload in patiens with thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with major thalassemia with regular blood transfusions; using iron chelating agents regularly; age above 7 years old. Exclusion criteria:

Patients who changed their chelating agents during the last 6 months; renal and hepatic failure; cardiac output less than 35%; systolic blood pressure less than 90 millimeter Hg, patients with HIV and hepatitis B and C.

Age
From **7 years** old to **54 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomize by table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City
Arak

Postal code
3819693345

Approval date
2015-05-27, 1394/03/06

Ethics committee reference number
IR.ARAKMU.REC.1394.41

Health conditions studied

1

Description of health condition studied
major thalassemia

ICD-10 code
D56.1

ICD-10 code description
Major thalassemia

Primary outcomes

1

Description
Ferritin Levels

Timepoint
Beginning and 1 and 6 and 12 months after treatment

Method of measurement
blood test

2

Description
Tissue iron level

Timepoint
Beginning, 6 months, 12months after treatment

Method of measurement
T2*MRI

Secondary outcomes

1

Description
Blood pressure

Timepoint
Monthly

Method of measurement
Barometer

Intervention groups

1

Description
Intervention group : previous chelating agents + Amlodipine، 5mg, daily, for 12 months,Abidi company

Category
Treatment - Drugs

2

Description
Control Group : previous chelating agents

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak Amirkabir Hospital

Full name of responsible person
Dr Eghbali Aziz

Street address
Amirkabir Hospital, Alamolhoda Street, Arak

City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Rafiee
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Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Grant name
_
Grant code / Reference number
_
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty