

# 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 for 12 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

##### Name

Aziz Eghbali

##### Name of organization / entity

دانشگاه علوم پزشکی اراک

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3465 5314

##### Email address

dr.eghbali@arakmu.ac.ir

#### 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 patients 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 squire, 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

**Street address**

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

**Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Aziz Eghbali

**Position**

Faculty, Pediatrics Oncologist

**Other areas of specialty/work****Street address**

Amirkabir Hospital, Alamalhoda street, Arak

**City**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

Dr Hamideh Kazemi

**Position**

Resident of pediatric

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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*