Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Pantaprazol on cardiac and hepatic iron overload assessd by T2* MRI in patient with major and intermediate Thalassemia

Protocol summary

Summary

Aim of this study is evaluation of Pantaprazol effect on cardiac &hepatic iron overload assessd by T2* MRI in patient with major and intermediate Thalassemia in Amirkabir hospital of Arak.This study clinical trials. Patients with more than 7 years divide in 2 groups. We measure Feritin and T2* MRI in cardiac and hepatic in two groups in first study. We prescribe 1 milligram in kilogram of Pantaprazol daily before breakfast(maximum dose 40 milligram) for 6 months in intervention group.We don't prescribe drug in control group. We measure Feritin and T2* MRI in cardiac and hepatic in two groups after 6 months. Inclusion criteria: Patients with major and intermediate Thalassemia; age more than 7 years Exclusion criteria: Drug intolerance; unwilling to participate in the study; heart failure; hepatitis; HIV

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042220258N40**
Registration date: **2017-09-03, 1396/06/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-03, 1396/06/12

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research,Arak University of Medical Sciences

Expected recruitment start date

2017-04-08, 1396/01/19

Expected recruitment end date

2018-05-09, 1397/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Pantaprazol on cardiac and hepatic iron overload assessd by T2* MRI in patient with major and intermediate Thalassemia

Public title

Evaluation of Pantaprazol on cardiac and hepatic iron overload in patient with major and intermediate Thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with major and intermediate Thalassemia; age more than 7 years Exclusion criteria: Drug intolerance; unwilling to participate in the study; heart failure; hepatitis; HIV

Age

From **7 years** old to **139 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomize with random numbers blindness: researcher than complete data don't aware grouping and analyzer don't aware grouping

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Arak University of Medical Sciences
Street address
Dr Mohammad Rafie, Vice Chancellor Research, Payambar Azam complex, Basij square, Sardasht, Arak
City
Arak
Postal code
38149578558
Approval date
2017-03-06, 1395/12/16
Ethics committee reference number
IR.ARAKMU.REC.1395.434

Health conditions studied

1

Description of health condition studied
major and intermediate Thalasemia
ICD-10 code
D56.1
ICD-10 code description
Beta thalassaemia

Primary outcomes

1

Description
Feritin in serum
Timepoint
before and 6 months after 6 treatment
Method of measurement
Blood test

2

Description
Heart and liver iron load
Timepoint
before and 6 months after 6 treatment
Method of measurement
MRI * 2T

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We prescribe 1 milligram in kilogram of Pantaprazol daily before breakfast (maximum dose 40 milligram) for 6 months in intervention group.
Category
Treatment - Drugs

2

Description
Intervention group: We don't prescribe drug in control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir hospital
Full name of responsible person
Dr Aziz Eghbali
Street address
Amirkabir hospital, Parastar square, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor forResearch, 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 forResearch, 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
Atefeh Khalilpour

Position
medicine student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position
Faculty, pediatric oncology

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)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty