Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the fffect of Defrasirox on MRIT2* and serum ferritin in major Thalassemia compared with Deferoxamine and Deferiprone in Gorgan Taleghani Hospital

Protocol summary

Summary

The aim of this study is evaluation of the effect of Defrasirox on MRIT2* and serum ferritin in major Thalassemia compared with Deferoxamine and Deferiprone in Gorgan Taleghani Hospital. In this study, 58 patients with major thalassemia who receive regular blood and serum ferritin levels below 5000 and treated with deferiprone with deferoxamine were randomly divided into 2 groups. in intervention group previous drug discontinuate and treatment with Defrosyroxe began. In control group continue previous drugs. At the beginning and end of one year, heart and liver MRI T2* and every three months serum ferritin level in all patients review. after one year, the result of this therapy on serum ferritin and cardiac and liver MRI T2* in patients with major thalassemia compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071823245N1**
Registration date: **2015-11-12, 1394/08/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-12, 1394/08/21

Registrant information

Name

Ghazal Vaseghi

Name of organization / entity

Golestan univercity of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Center of Golestan University Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the fffect of Defrasirox on MRIT2* and serum ferritin in major Thalassemia compared with Deferoxamine and Deferiprone in Gorgan Taleghani Hospital

Public title

Effect of Defrasirox on ferritin and iron overload in Thalassemia Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with major thalassemia with blood transfusions and treatment with Deferiprone with Deferoxamine; Ferritin levels below 5000ng/ml. Exclusion criteria:The patient dissatisfaction; drug intolerance.

Age

No age limit

Gender

Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
University ethics committee of Golestan University of Medical Sciences
Street address
Golestan University of Medical Sciences, beginning Shastkola road, 5 km Sari Gorgan road
City
Gorgan
Postal code
Approval date
2015-03-15, 1393/12/24
Ethics committee reference number
1107869312247

Health conditions studied

1

Description of health condition studied
major thalassemia
ICD-10 code
D56.9
ICD-10 code description
Thalassemia, unspecified

Primary outcomes

1

Description
serum ferritin
Timepoint
Baseline, 3 month6month,9month,12month
Method of measurement
sampling and serum ferritin level(ng/ml)

2

Description
changes of MRI T2* normally, involves mild, moderate, severe
Timepoint
baseline, after one year
Method of measurement
MRI and The speed Back in phase T2* With millisecondand and classificate into four groups: normal, mild, moderate, severe

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group previous treatment will be discontinued and patient will be treated with Defrosiroxe 20-40 mg/ kg/ day for one year
Category
Treatment - Drugs

2

Description
The control group will be treated with Deferoxamine 20-60 mg/ kg/ day in three doses with or without of Deferiprone 50-100 mg/ kg/ day in three doses
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgn Taleghani Hospital
Full name of responsible person
Ghazal Vseghi
Street address
Taleghani Hospital, Janbazan Blvd, Gorgan city, Golestan
City
Gorgan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Center of Golestan University of Medical Sciences

Full name of responsible person
miss Nazari
Street address
Vice Chancellor for Research and Technology of Golestan Univercityof Medical Sciences, beginning of Shastkola road, 5 km Sari Gorgan road
City
Gorgan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Center of Golestan 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
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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