

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect 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 discontinue and treatment with Defrosyrox 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 university of Medical Science

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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 effect 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 Shaskola 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 month, 6 month, 9 month, 12 month

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 millisecond and classify 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 Deferosirox 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 University of 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**

Golestan University of Medical Sciences

Full name of responsible person

Ghazal Vaseghi

Position

Resident of pediatrics

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Associate Professor

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Taleghani Hospital

Full name of responsible person

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Web page address**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