Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial in evaluation of the efficacy of defroxamine-deferiprone on cardiac function in patients with major thalassemia

Protocol summary

Summary

The aim of this study is to determine the effect of deferiprone-deferoxamine on cardiac function of patients with major thalassemia . Inclusion criteria are treating with iron chelators subcutaneous deferoxamine to 5 nights a week (with a dose of 50-30 micrograms per kilogram) for 3 years and exclusion criteria are gastrointestinal complications, failure to cooperate in the control tests (ALT, CBC) and becoming tired of the traffic for controlling consumption of deferiprone. 12 patients with beta major thalassemia referred to Gorgan Taleghani Hospital that were treated by subcutaneous deferoxamine with a dose of 30-50 mg/kg for 5 nights a week for 3 years , chocardiography will be done for them and LVEF (The amount of blood that comes out every beat of the heart) and serum ferritin will be determined. Then these patients are treated by deferiprone with dosage of 50-100 mg/kg daily and dferoxamine with dosage of 30-50 mg/kg for 3 nights a week for 3 years. At the end of each year, echocardiography is performed and LVEF and serum ferritin are determined for patients. Finally, The LVEF and serum ferritin values obtained within three years will be compared with baseline values.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070512765N4**
Registration date: **2014-08-08, 1393/05/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-08, 1393/05/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Sciences

Expected recruitment start date

2010-02-23, 1388/12/04

Expected recruitment end date

2013-03-18, 1391/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial in evaluation of the efficacy of defroxamine-deferiprone on cardiac function in patients with major thalassemia

Public title

Evaluation of the efficacy of defroxamine- deferiprone on cardiac function in patients with thalassemia major

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients were treated with iron chelators Subcutaneous Deferoxamine with a doseof 30-50 mg/kg for 5 nights a week for 3 years before starting the study. Exclusion criteria: gastrointestinal

complications; failure to cooperate in the control tests (ALT, CBC); becoming tired of the traffic for controlling consumption of deferiprone

Age
From **2 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **12**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Golestan University of Medical Sciences

Street address
Falsafi Higher Education Bilding, Bigining of Shastkola Roade

City
Gorgan

Postal code

Approval date
2010-02-21, 1388/12/02

Ethics committee reference number
3817138812022

Health conditions studied

1

Description of health condition studied
Thalassemia major

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia major

Primary outcomes

1

Description
Left Venticular Ejection Fraction

Timepoint
It is messured for 3 years at the end of each year.

Method of measurement
Echocardiography

2

Description
Srum ferritin

Timepoint
It is messured for 3 years at the end of each year.

Method of measurement
Determining the level of serum ferritin by related test

Secondary outcomes

empty

Intervention groups

1

Description
Treatment by Deferiprone with a dose of 50-100 mg/kg daily associated with treatment by Deferoxamine with a dose of 50-30 mg/kg for 3 nights weekly

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hematology and Oncology Research Center

Full name of responsible person
Narges beigom Mirbehbahani

Street address
Taleghani Hospital, Janbazan Boulevard

City
Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Golestan University of Medical Sciences

Full name of responsible person
Dr. Masoud Khoshnia

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Falsafi Higher Education Bilding, Bigining of Shastkola Roade

City
Gorgan

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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

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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