

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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, echocardiography 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 deferoxamine 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

Name

Azam Rashidbaghan

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1232 8539

Email address

hocr@goums.ac.ir

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 dose of 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 Ventricular Ejection Fraction

Timepoint

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

Method of measurement

Echocardiography

2

Description

Srum ferritin

Timepoint

It is measured 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

Street address

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

Hematology & Oncology Research Center, Golestan University of Medical Sciences

Full name of responsible person

Narges beigom Mirbehbahani

Position

Associate Professor

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

Taleghani Hospital, Janbazan Boulevard

City

Gorgan

Postal code**Phone**

+98 17 1232 8539

Fax

+98 17 1232 8539

Email

n.mirbehbahani@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hematology and Oncology Research Center, Golestan University of Medical Sciences

Full name of responsible person

Narges beigom Mirbehbahani

Position

Associate Professor

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

Taleghani Hospital, Janbazan Boulevard

City

Gorgan

Postal code**Phone**

+98 17 1232 8539

Fax

+98 17 1232 8539

Email

n.mirbehbahani@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Hematology and Oncology Research Center, Golestan University of Medical Sciences

Full name of responsible person

Azam Rashibaghan

Position

MSc./ research expert of Hematology and Oncology Research Center

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

Taleghani Hospital, Janbazan Boulevard

City

Gorgan

Postal code**Phone**

+98 17 1232 8539

Fax

+98 17 1232 8539

Email

rashidbaghan@yahoo.com

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*