

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 &amp; 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*