

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of Iron Chelation Effects of Deferoxamine, Deferasirox, and Combination of Deferoxamine and Deferiprone in Thalassemia Major

Protocol summary

Summary

Beta thalassemia is a hereditary disorder of hemoglobin that results in impaired synthesis of beta-globin chains, leading to hemolytic anemia. Regular blood transfusion is essential for long-term survival of patients, but iron overload occurs gradually in various tissues. Heart disease is most common cause of death in these patients due to iron deposition in the heart muscle. The MRI T2 * as a non-invasive method for quantitative measurement of cardiac iron can be used to follow response to iron chelator therapy. The aim of this study was to compare the effect of Deferoxamine , Deferasirox, and combination therapy of Deferoxamine and deferiprone on cardiac iron burden as measured by MRI T2 * in thalassemia major patients at Ali Asghar Children's Hospital and Zafar clinic of adult thalassemia .

+98 21 2304 6411

Email address

mirialiabad@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091710862N1**

Registration date: **2013-06-20, 1392/03/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-20, 1392/03/30

Registrant information

Name

Ghasem Mirialiabad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

Scientific title

Comparison of Iron Chelation Effects of Deferoxamine, Deferasirox, and Combination of Deferoxamine and Deferiprone in Thalassemia Major

Public title

Iron Chelators Effects in Thalassemia Major

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: transfusion dependent thalassemia with age over 10 years;cardiac iron load on MRI T2 *

Exclusion criteria : severe hepatic disorder; renal disease; history of neutropenia; history of adverse reactions to any of chelators in the past; failure to perform MRI T2 * due to causes such as pacemakers; pregnancy; fear of closed environment

Age

From **10 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 108

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

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-06-20, 1391/03/31

Ethics committee reference number

91/130/385/5

Health conditions studied

1

Description of health condition studied

Major thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

serum ferritin, ng/ml

Timepoint

0 and 12 month later

Method of measurement

RIA

Secondary outcomes

1

Description

Cardiac Iron Load

Timepoint

0 and 12 month later

Method of measurement

Cardiac MRI T2*

Intervention groups

1

Description

The first group was treated with subcutaneous infusion of 30-50 mg/kg/day deferoxamine during 8-12 hours for at least 5-6 nights a week using a pump for at least one year

Category

Treatment - Drugs

2

Description

The second group received 20-40 mg/kg/day deferasirox as a single oral dose before the first meal for at least one year.

Category

Treatment - Drugs

3

Description

The third group was treated with subcutaneous infusion of 30-50 mg/kg/day deferoxamine during 8-12 hours for at least 5-6 nights a week using a pump and 75-100 mg/kg/day oral deferiprone in three divided doses for at least one year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Children's Hospital and adult thalassemia clinic of Zafar

Full name of responsible person

Ghasem Mirialiabad

Street address

No. 193, Dastgerdi St, Shariati St, Ali Asghar Children's Hospital, Tehran University of Medical Sciences and Health Services, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences Vice chancellor for research

Full name of responsible person

Dr. Akbar Fotouhi (Research Deputy of Tehran University of Medical Sciences)

Street address

Central Organization of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences Vice chancellor for research

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**

Tehran University of Medical Sciences

Full name of responsible person

Shahla Ansari

Position

Associate professor of pediatric

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

No. 193 , Dastgerdi St, Shariati St, Ali Asghar Children's Hospital, Tehran University of Medical Sciences and Health Services, Tehran, Iran.

City

Tehran

Postal code**Phone**

+98 21230461411

Fax**Email**

shahladamavandi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shahla Ansari

Position

associate professor of pediatric

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

No. 193 , Dastgerdi St, Shariati St, Ali Asghar Children's Hospital, Tehran University of Medical Sciences and Health Services, Tehran, Iran.

City

Tehran

Postal code**Phone**

+98 21 2304 6411

Fax**Email**

shahladamavandi@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ghasem Miri-Aliabad

Position

Fellowship of pediatric oncology

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

No. 193 , Dastgerdi St, Shariati St, Ali Asghar Children's Hospital, Tehran University of Medical Sciences and Health Services, Tehran, Iran.

City

Tehran

Postal code**Phone**

+98 21 2304 6411

Fax**Email**

gh_miri@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