Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

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 gradualy 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 .

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 Scienses

Country

Iran (Islamic Republic of)

Phone

+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

Scientific title

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

Public title

Iron Chelators Effects in Thalassemia Maior

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/د

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
srum 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 pumpfor 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 meafor at least one year l.
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