Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A clinical trial comparing the effectiveness of deferoxamine–deferasirox, deferasirox–deferiprone, and deferoxamine–deferiprone combinations in patients with beta-thalassemia major and severe iron overload

Protocol summary

Study aim
To compare the effectiveness of deferoxamine–deferasirox, deferasirox–deferiprone, and deferoxamine–deferiprone combinations in patients with beta-thalassemia major and severe iron overload

Design
A clinical trial with three intervention groups, parallel design, non-randomized, single-blinded, will be conducted on 105 patients.

Settings and conduct
Patients with beta-thalassemia and severe iron overload, selected at Dr. Sheikh Hospital in Mashhad, will be non-randomly assigned to three treatment groups. The study is single-blinded, meaning that the data collectors are unaware of which participants are in which group and of the type of treatment method.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Children with beta-thalassemia major and severe iron overload who have not achieved adequate iron control with monotherapy; age above 5 years; severe iron overload defined as serum ferritin greater than 2500 ng/dl or severe/very severe iron overload reported in cardiac and hepatic MRI. Exclusion criteria: Having chronic infectious diseases such as hepatitis; having proteinuria; having study drugs allergies.

Intervention groups
Group 1: Deferasirox (oral tablet, 14–28 mg/kg once daily for ≥6 months) plus Deferoxamine (subcutaneous infusion, 30–50 mg/kg over 8–12 hours, at least 5 times per week for ≥6 months). Group 2: Deferasirox (oral tablet, 14–28 mg/kg once daily for ≥6 months) plus Deferiprone (oral tablet, 75–80 mg/kg in three divided doses daily for ≥6 months). Group 3: Deferoxamine (subcutaneous infusion, 30–50 mg/kg over 8–12 hours, at least 5 times per week for ≥6 months) plus Deferiprone (oral tablet, 75–80 mg/kg in three divided doses daily for ≥6 months).

Main outcome variables
Serum ferritin levels, hepatic and cardiac iron concentrations

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251214068323N1**
Registration date: **2026-01-07, 1404/10/17**
Registration timing: **prospective**

Last update: **2026-01-07, 1404/10/17**
Update count: **0**

Registration date
2026-01-07, 1404/10/17

Registrant information

Name
Hamid Farhangi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2027-01-21, 1405/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effectiveness of deferoxamine–deferasirox, deferasirox–deferiprone, and deferoxamine–deferiprone combinations in patients with beta-thalassemia major and severe iron overload

Public title

The effectiveness of drug combination in patients with beta-thalassemia major and severe iron overload

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with beta-thalassemia major and severe iron overload who have not achieved adequate iron control with monotherapy. Age above 5 years Severe iron overload defined as serum ferritin greater than 2500 ng/dl or severe/very severe iron overload reported in cardiac and hepatic MRI Absence of congenital heart disease Absence of chronic viral hepatitis infection Absence of heart failure

Exclusion criteria:

Having chronic infectious diseases such as hepatitis Serum creatinine level increased by more than 25% above baseline Having proteinuria ALT level elevated more than five times the normal value Having study drugs allergies

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The data collectors are blinded to group allocation and treatment method.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Faculty of Medicine, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2025-11-04, 1404/08/13

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1404.420

Health conditions studied

1

Description of health condition studied

Beta-thalassemia major

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

Serum ferritin levels

Timepoint

1, 2 and 3 months after intervention

Method of measurement

ELISA Ferritin Assay Kit

2

Description

Hepatic iron concentration

Timepoint

12 months after intervention

Method of measurement

Magnetic resonance imaging (MRI)

3

Description

Cardiac iron concentration

Timepoint

12 months after intervention

Method of measurement

Magnetic resonance imaging (MRI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Patients in this group will receive Deferasirox (oral tablet, 14–28 mg/kg once daily for at least six months). Deferasirox is an oral iron chelator manufactured by Novartis, widely used to reduce iron overload resulting from frequent blood transfusions.In addition, they will be treated with Deferoxamine (subcutaneous infusion, 30–50 mg/kg administered over 8–12 hours, at least five times per week, for a minimum of six months). Deferoxamine is an injectable iron chelator, typically delivered via a portable infusion pump, and is also produced by Novartis. This drug is specifically indicated for lowering iron burden in patients with thalassemia major.

Category

Treatment - Drugs

2

Description

Intervention Group 2: Patients in this group will receive Deferasirox (oral tablet, 14–28 mg/kg once daily for at least six months). Deferasirox is an oral iron chelator manufactured by Novartis, commonly prescribed to reduce iron overload in transfusion-dependent thalassemia patients.In addition, they will be treated with Deferiprone (oral tablet, 75–80 mg/kg per day, administered in three divided doses, for a minimum of six months). Deferiprone is another iron chelator, typically produced by Apotex, and is widely used in combination therapy to enhance iron removal from both plasma and intracellular compartments.

Category

Treatment - Drugs

3

Description

Intervention Group 3: Patients in this group will receive Deferoxamine at a dose of 30 to 50 mg/kg body weight, administered as a subcutaneous infusion over 8 to 12 hours, at least 5 times per week, for a minimum duration of 6 months. Deferoxamine is an injectable iron chelator, typically delivered via a portable infusion pump, and manufactured by Novartis. This drug is specifically indicated for reducing iron stores in patients with thalassemia major.In addition, patients will receive Deferiprone as an oral tablet at a dose of 75 to 80 mg/kg body weight per day, divided into 3 daily doses, for at least 6 months. Deferiprone is an oral iron chelator, commonly produced by Apotex, and is particularly used to enhance iron excretion from plasma and intracellular compartments.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Sheikh Hospital

Full name of responsible person
Hamid Farhangi

Street address
Dr. Sheikh Pediatric Subspecialty Hospital, Dr. Sheikh Street, Tohid Square

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Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodii

Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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91778 99191

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vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Farhangi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable

Hamid Farhangi provides the data analysis to the applicants via email: farhangih@mums.ac.ir

What processes are involved for a request to access

data/document

Applicants can send a message to the respondent's email and will receive a reply within one week.

Comments