

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Compare the efficacy of combination Deferasirox and Deferiprone with Deferoxamine and Deferiprone in reducing heart and liver iron load in patients with transfusion-Dependent β -Thalassemia.

Protocol summary

Study aim

The efficacy of combination of Deferasirox and Deferiprone in reducing iron load in patients with transfusion-Dependent β -Thalassemia

Design

Randomized,controlled clinical trial with a parallel group

Settings and conduct

This randomized clinical trial were don in 107 patients with transfusion-Dependent β -Thalassemia in thalassemia center of Isfahan, Omid hospital. all patient divided in two group ,group A (Defrasirox and Deferiprone) and group B (Defroxamin and Deferiprone), and investigated for six month.Heart and Liver MRI T2* were done before treatment and at the end of study. ferritin level befor treatment and every three month measured. Change in ferritin level and Heart and liver iron concentration before and after treatment compare between two group

Participants/Inclusion and exclusion criteria

Age more than 10, Ferritin more than 1000, Heart and Liver iron load mild moderate and severe, Not receiving combination therapy and Liver and Renal normal function

Intervention groups

Group A: Deferasirox and Deferiprone group that Treat with Deferasirox and Deferiprone for six month Group B:Defroxamin and Deferiprone group that Treat with Defroxamin and Deferiprone for six month

Main outcome variables

Heart and liver MRI T2*,Ferritin level, Liver function test, Renal function test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190106042262N1**

Registration date: **2019-03-02, 1397/12/11**

Registration timing: **retrospective**

Last update: **2019-03-02, 1397/12/11**

Update count: **0**

Registration date

2019-03-02, 1397/12/11

Registrant information

Name

Ali Reza Fazeli Varzaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3527 6082

Email address

rezaali.fazeli6768@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2018-02-19, 1396/11/30

Actual recruitment end date

2018-05-22, 1397/03/01

Trial completion date

2018-12-21, 1397/09/30

Scientific title

Compare the efficacy of combination Deferasirox and Deferiprone with Deferoxamine and Deferiprone in reducing heart and liver iron load in patients with

transfusion-Dependent β -Thalassemia.

Public title

Compare the efficacy of combination therapy of Deferasirox and Deferiprone in reducing iron load in patients with transfusion-Dependent β -Thalassemia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All Patients with transfusion-Dependent β -Thalassemia with ferritin more than 1000 All Patients with transfusion-Dependent β -Thalassemia who were not treated with combination iron chelators All Patients with transfusion-Dependent β -Thalassemia with heart and liver iron load All Patients with transfusion-Dependent β -Thalassemia with normal liver and renal function All Patients with transfusion-Dependent β -Thalassemia with age more than 10 years

Exclusion criteria:

Gastrointestinal problem before research

Age

From **10 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Actual sample size reached: **107**

Randomization (investigator's opinion)

Randomized

Randomization description

All samples encoded by a third person that does not participate in the research, and then by using a random digits table, patients were divided into two groups

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

- Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

8375174647

Approval date

2018-02-25, 1396/12/06

Ethics committee reference number

397106

Health conditions studied

1

Description of health condition studied

transfusion-Dependent β -Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Heart and liver iron concentration

Timepoint

At the start of research and six month later

Method of measurement

Magnetic resonance imaging T2*

Secondary outcomes

1

Description

Ferritin

Timepoint

At the start of research and third and sixth of study

Method of measurement

Serum ferritin level

Intervention groups

1

Description

Intervention group: for six month treated with Deferasirox (in this study we use Osveral 125mg, 250 and 500mg construction of Osvah Company of Iran) with 20-40 mg/kg daily and Deferiprone (construction of avicenna Company of Iran) with 15 mg/kg/dose in three dose

Category

Treatment - Drugs

2

Description

Control group: for six month treated with Defroxamin(Vial 500mg) with 20-50 mg/kg daily that

infusion with a pump and Deferiprone (construction of avicenna Company of Iran) with 15 mg/kg/dose in three dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Thalasemia center of Omid Hospital of Isfahan

Full name of responsible person

Alireza Fazeli varzaneh

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Motahari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

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Phone

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vcr-office@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Fazeli Varzaneh

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Medical doctor

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

After the completion of the study, the protocol of study and the statistical analysis map, as well as all the data collected, including the individual data of the participants after unidentifiable people and main outcome will be presented in tables and diagrams in Result section of article.1

When the data will become available and for how long

Immediately after the publication of result

To whom data/document is available

Everyone is able to access

Under which criteria data/document could be used

For more study on patients with β -Thalassemia

From where data/document is obtainable

Refer to email: Rezaali.fazeli6768@gmail.com

What processes are involved for a request to access data/document

After receiving a request email, documentation will be sent within one week

Comments