Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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+98 31 3527 6082

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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
Isfehan
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 Defrasirox (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 pomp 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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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