Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A comparative study on efficacy of Deferasirox (Exjade) versus Osveral in treatment of iron overload in patients with beta thalassemia major

Protocol summary

Summary

Objectives: The goal of this study was to compare the efficacy of Osveral and Exjade in reducing iron overload of liver and heart and serum ferritin. Design: This non-randomized RCT study was done in Mofid hospital. All patients with beta thalassemia in Mofid pediatric hospital in 1394 that did not have compliance of iron injection were enrolled the study.The patients were allocated to exjade and osveral groups according to economic level.Because the low economic level participants could not afford to buy exjade. This study was single center and 2th phase of clinical trial. Setting and conduct: Inclusion criteria included equal or more than 2 years old, normal creatinine(cr) level, no proteinuria, negative for hepatitis B and C or HIV, hepatic transaminase less than 5 time above normal values, the ferritin level more than 1000 and transfusion more than 10 times.Exclusion criteria included severe heart failure, liver transaminase more than five folds, repeated cytopenia, nausea and vomiting, skin rashes and elevated serum Cr. Intervention: The data belongs to two groups of people who received Deferasirox or Osveral as an iron chelator were gathered and analyzed. The duration of patient follow up was 12 months. Main outcome measures: The ferritin level of serum was checked at the biginning of the study and every three months. The heart and liver MRI T2* findings were assessed before and after our intervention to confirm as the most sensitive ways of liver and heart iron load.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102524679N2**
Registration date: **2016-06-16, 1395/03/27**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-06-16, 1395/03/27

Registrant information

Name
Samin Alavi
Name of organization / entity
Mofid Hospital
Country
Iran (Islamic Republic of)
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+98 21 2222 7021
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on efficacy of Deferasirox (Exjade) versus Osveral in treatment of iron overload in patients with beta thalassemia major

Public title

Effect of Osveral on iron overload in beta thalassemia major patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: equal or more than 2 years old; normal creatinine level; no proteinuria; negative for hepatitis B and C or HIV; hepatic transaminase less than 5 time above normal values; nornal CBC; No cardiac disorder; the ferritin level more than 1000; transfusion more than 10 times. Exclusion criteria: severe heart failure; patients who can not tolerate MRI; keeping liver transaminase more than five folds; repeated cytopenia; nausea and vomiting; skin rashes; and elevated serum creatinine.

Age

To **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **69**

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, velenjak

City

Tehran

Postal code

Approval date

2013-02-28, 1391/12/10

Ethics committee reference number

18227

Health conditions studied

1

Description of health condition studied

beta thalassemia

ICD-10 code

D56.1

ICD-10 code description

beta thalassemia

Primary outcomes

1

Description

serum ferritin

Timepoint

before the intervention and every 3 monthes

Method of measurement

ELISA method, ng/ml

2

Description

The liver iron overloads

Timepoint

at the biginning of the intervention and after 12 monthes

Method of measurement

MRI T2

3

Description

The heart iron overloads

Timepoint

at the biginning of the intervention and after 12 monthes

Method of measurement

MRI T2

Secondary outcomes

1

Description

AST

Timepoint

at the biginning of the study and every 3 monthes

Method of measurement

Specterophotometery method, mIU/l

2

Description

ALT

Timepoint

at the biginning of the study and every 3 monthes

Method of measurement

Specterophotometery method, mIU/l

3

Description

serum Creatinin

Timepoint

at the biginning of the study and every 3 monthes

Method of measurement

Jaffeh method, mg/dl

4

Description
urine Creatinin
Timepoint
at the biginning of the study and every 3 monthes
Method of measurement
mg/dl

5

Description
urine Pr
Timepoint
at the biginning of the study and every 3 monthes
Method of measurement
mg/dl

Intervention groups

1

Description
Intervention group 1: Osveral (Iron chelating agent, Osveh Company, Iran) was given as follows. The starting dose was 20 mg/kg/d for Osveral and the ferritin level measured each three months up to twelve months. The dose of drugs tailored to ferritin level for each patients at the rate of 5-10 mg/kg/d
Category
Treatment - Drugs

2

Description
Intervention group 2: Ḍeferasirox (Exjade, Iron chelator agent, Novartis company, Switzerland) was given to this group. The starting dose was 20 mg/kg/d for Deferasirox and the ferritin level measured each three months up to 12 months. The dose of drugs tailored to ferritin level for each patients at the rate of 5-10 mg/kg/d
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Hospital, Thalassemia Center
Full name of responsible person
Dr. Neda Ashayeri
Street address
Below the Mirdamad street, Shariati street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
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
Investigator
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
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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