

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 beginning 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)

###### Phone

+98 21 2222 7021

###### Email address

s.alavi@sbmu.ac.ir

##### 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; normal 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 beginning of the intervention and after 12 monthes

#### **Method of measurement**

MRI T2

### **3**

#### **Description**

The heart iron overloads

#### **Timepoint**

at the beginning of the intervention and after 12 monthes

#### **Method of measurement**

MRI T2

## **Secondary outcomes**

### **1**

#### **Description**

AST

#### **Timepoint**

at the beginning of the study and every 3 monthes

#### **Method of measurement**

Specterophotometry method, mIU/l

### **2**

#### **Description**

ALT

#### **Timepoint**

at the beginning of the study and every 3 monthes

#### **Method of measurement**

Specterophotometry method, mIU/l

### **3**

#### **Description**

serum Creatinin

#### **Timepoint**

at the beginning of the study and every 3 monthes

#### **Method of measurement**

Jaffeh method, mg/dl

#### 4

##### **Description**

urine Creatinin

##### **Timepoint**

at the beginning of the study and every 3 monthes

##### **Method of measurement**

mg/dl

#### 5

##### **Description**

urine Pr

##### **Timepoint**

at the beginning 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: Deferasirox (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**

Dr. Neda Ashayeri

###### **Street address**

Mofid hospital. Shariati St, Tehran

###### **City**

Tehran

##### **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**

Mofid Hospital

###### **Full name of responsible person**

Neda Ashayeri

###### **Position**

Pediatricion

###### **Other areas of specialty/work**

###### **Street address**

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## **Person responsible for scientific inquiries**

##### **Contact**

###### **Name of organization / entity**

Shahid beheshti university of medical sciences

###### **Full name of responsible person**

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pediatric hematology and oncology

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**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*

**Person responsible for updating data****Contact****Name of organization / entity**

Mofid Hospital

**Full name of responsible person**

Dr. Neda Ashayeri

**Position**

Pediatrician

**Other areas of specialty/work****Street address**