Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of the efficacy of Iranian Deferasirox (Osveral®) and Exjade® on serum ferritin in patients with major beta-thalassemia

Protocol summary

Study aim
The comparison of the efficacy of Iranian Deferasirox (Osveral®) and Exjade® on serum ferritin in patients with major beta-thalassemia

Design
Phase II randomized open-label clinical trial

Settings and conduct
This study was conducted on β-thalassemia major patients, who attended to thalassemia center of Bu-Ali Sina hospital in Sari, Iran.

Participants/Inclusion and exclusion criteria
The criteria for screening and entering the study were male or female patients with β-thalassemia major; age>2 year; ferritin level above 1000 mg/dL or the volume of blood transfusion above 100 mL/kg. All patients with pregnancy or breast-feeding state; progressive or persistent increase in the creatinine level; any cardiac, auditory or ophthalmic problems; hepatitis B or C, and HIV; persistent liver transaminases above 5-fold of the normal level; severe nausea and vomiting; hypersensitivity to deferasirox; severe skin rashes, progressive proteinuria and non-compliant or unreliable patients were excluded.

Intervention groups
The patients of Group 1 were received Osveral® and group 2 received Exjade®

Main outcome variables
The mean changes in serum ferritin concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090813002342N9**
Registration date: **2018-10-23, 1397/08/01**
Registration timing: **retrospective**
Last update: **2018-10-23, 1397/08/01**
Update count: **0**

Registration date
2018-10-23, 1397/08/01

Registrant information

Name
Mohammad Reza Rafati

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 15 1354 3083

Email address
mrrafati@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-03-30, 1394/01/10

Expected recruitment end date
2016-04-19, 1395/01/31

Actual recruitment start date
2015-08-03, 1394/05/12

Actual recruitment end date
2016-09-01, 1395/06/11

Trial completion date
2016-11-01, 1395/08/11

Scientific title
The comparison of the efficacy of Iranian Deferasirox (Osveral®) and Exjade® on serum ferritin in patients with major beta-thalassemia

Public title
The efficacy of Iranian Deferasirox (Osveral®) and Exjade® in the treatment of patients with major beta-thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female patients with β-thalassemia major Age>2 year Ferritin level above 1000 mg/dL or the volume of blood transfusion above 100 mL/kg

Exclusion criteria:

Patients with pregnancy or breast-feeding state Progressive or persistent increase in the creatinine level Any cardiac, auditory or ophthalmic problems Hepatitis B (HBV) or C (HCV) and human immunodeficiency virus (HIV) infections Persistent liver transaminases above 5-fold of the normal level Severe nausea and vomiting Hypersensitivity to deferasirox Sever skin rashes Progressive proteinuria Non-compliant or unreliable patients

Age

From **2 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was used to randomize patients to receive either Osveral® or Exjade®. Patients eligible for inclusion in the study were randomly assigned based on the random number table.

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 Mazandaran University of Medical Sciences

Street address

Payambar Azam Complex, 18 Km Farah Abad Blvd., Khazar Square, Sari, Mazandaran Province

City

Sari

Province

Mazandaran

Postal code

861-48175

Approval date

2015-08-31, 1394/06/09

Ethics committee reference number

IR.MAZUMS.REC 94-1069

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

changes in serum ferritin concentration

Timepoint

bimonthly along 6 months

Method of measurement

Laboratory measurement of serum ferritin level

Secondary outcomes

1

Description

Mean changes of cardiac and liver MRI T2*

Timepoint

Baseline and a year after starting of the treatments

Method of measurement

Measurement of T2* by Magnetic Resonance Imaging (MRI)

2

Description

Drug safety and tolerability

Timepoint

Every two months to one year after treatment

Method of measurement

Question from patient and examination

Intervention groups

1

Description

Intervention group 1: Iranian Deferasirox (Osveral®), dose 30 mg/kg/day, single daily dose, half an hour before breakfast, for 6 months, made by Osvah Pharmaceutical Company

Category

Treatment - Drugs

2

Description
Intervention group 2: Exjade®, dose 30 mg/kg/day, single daily dose, half an hour before breakfast, for 6 months, made by Novartis Company
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu-Ali Sina hospital
Full name of responsible person
Dr. Mohammad Reza Rafati
Street address
Bu-Ali Sina Hospital, Pasdaran Blvd., Sari, Mazandaran, Iran
City
Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 11 3334 7837
Email
mrrafati@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeedi
Street address
Mazandaran University of Medical Sciences, Deputy of Research and Technology, Moallem Square, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4817844718
Phone
+98 11 3448 4800
Email
majsaeedi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rafati
Position
Associate Professor of Clinical Pharmacy
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province
City
Sari
Province
Mazandaran
Postal code
861-48175
Phone
+98 11 3354 3081
Email
mrrafati@mazums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rafati
Position
Associate Professor of Clinical Pharmacy
Latest degree
Specialist
Other areas of specialty/work
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Street address
Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province
City
Sari
Province
Mazandaran

Postal code
861-48175
Phone
+98 11 3354 3081
Email
mrrafati@mazums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rafati
Position
Associate Professor of Clinical Pharmacy
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province
City
Sari
Province
Mazandaran
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861-48175
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Email
mrrafati@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No sufficient permission has been obtained to disseminate patient information.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable