

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

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+98 15 1354 3083

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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

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4815838477

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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

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Mazandaran University of Medical Sciences, Deputy of Research and Technology, Moallem Square, Sari, Iran

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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

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

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Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province

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Web page address

Person responsible for scientific inquiries

Contact

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

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Mazandaran Province**City**

Sari

Province

Mazandaran

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPDNo 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