Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison the efficacy of Deferoxir versus other desferoxamine products in thalassemia major patient

Protocol summary

Summary
This study aims to compare and evaluate the efficacy and side effects of Defroxir with other valid deferoxamine mesilate products of Iran pharmaceutical industries. This is a multicenter, Before-After study on 100 patients (25 subjecta in each center) undergoing one of the stable valid deferoxamine products such as (desfral,desfonac,desferoxamine and etc...).Eligible participants include major thalassemic patients under regular blood injection therapy over 5 years old. After the first 6 months, every 25 patients under treatment with one of the stable valid deferoxamine products passing the wash out period and change to second phase including treatment with Defroxir therapy. The measurements will be tested in month 0 (start of first phase treatment), month 6 (change in treatment) and month 12 (end of treatment). The mean change of repeated measurement will be considered as efficacy results.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2015012620818N1**
Registration date: **2015-02-26, 1393/12/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2015-02-26, 1393/12/07

Registrant information
Name
Narges Jowzi
Name of organization / entity
Exir pharmacutical company
Country
Iran (Islamic Republic of)
Phone
+98 88918467
Email address
info@exir.co.ir

Recruitment status
Recruitment complete
Funding source
Exir pharmacutical company

Expected recruitment start date
2014-09-23, 1393/07/01
Expected recruitment end date
2015-10-22, 1394/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the efficacy of Deferoxir versus other desferoxamine products in thalassemia major patient

Public title
Exir research project of desferoxamin with brand name of Deferoxir
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients with major thalassemia under regular blood injection therapy;. age over 5; undergoing treatment with one of deferoxamine pharmaceutical products; Norma renal function; serum cratinine undr 0. 7; in children under the age of 12 less than 1.0; in teenagers less than 1.1; and in over 16 years old pateinets (female less than 1.2; male less than 1.2); Trans aminase enzymes level less than 2 times of normal range; BUN<22mg/dl. Exclusion Criteria: Any experience

of allergic reaction to desferoxamine, positive HCV Ab / HBS Ag.

Age
From **5 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
institue of research and education of blood transfusion medicine

Street address
Iran blood transfusion organization-beside milad-tower,Hemmat highway intersection of Fazlollahe-noori Highway

City
tehran

Postal code
14665-1157

Approval date
2014-11-23, 1393/09/02

Ethics committee reference number
26352

Health conditions studied

1

Description of health condition studied
thalassemia major

ICD-10 code
D56

ICD-10 code description
Cooley anaemia Severe beta thalassaemia Thalassaemia: intermedia major

Primary outcomes

1

Description
ferritin

Timepoint
every 2 month from begining of study

Method of measurement
blood test

2

Description
SGOT

Timepoint
every 2 month from begining of study

Method of measurement
blood test

3

Description
SGPT

Timepoint
every 2 month from begining of study

Method of measurement
blood test

4

Description
Cr

Timepoint
every 2 month from begining of study

Method of measurement
blood test

5

Description
WBC

Timepoint
every 2 weeks

Method of measurement
blood test

6

Description
Hgb

Timepoint
every 2 weeks from begining of study

Method of measurement
blood test

7

Description
Platlet

Timepoint
every 2 weeks from begining of study

Method of measurement

blood test

Secondary outcomes

1

Description
optometry
Timepoint
before study,6 months after begining of study,12 months after beginig of study
Method of measurement
optometry

2

Description
T2*MRI
Timepoint
before study,6 months after begining of study,12 months after beginig of study
Method of measurement
blood test

3

Description
Audiology
Timepoint
before study,6 months after begining of study,12 months after beginig of study
Method of measurement
Audiology

4

Description
Sonography
Timepoint
before study,6 months after begining of study,12 months after beginig of study
Method of measurement
Sonography

Intervention groups

1

Description
Deferoxir vial 500 mg,40 mg/kg,for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zafar thalassemia clinic
Full name of responsible person
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Shiraz thalassemia research center
Full name of responsible person
Street address
City
Shiraz

3

Recruitment center
Name of recruitment center
Ahvaz thalassemia research center
Full name of responsible person
Street address
City
Ahvaz

4

Recruitment center
Name of recruitment center
kerman thalassemia clinic
Full name of responsible person
Street address
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
exir pharmacutical company
Full name of responsible person
Dr Mir Azizi
Street address
N 22,rahmati alley,before Zartosht street,above valieasr sq
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
exir pharmacutical company
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
Exir pharmacutical company
Full name of responsible person
Dr Mir Azizi
Position
clinical research manager
Other areas of specialty/work
Street address
N 22,rahmati alley,before Zartosht street,above valieasr sq
City
Tehran
Postal code
Phone
+98 21 8891 8475
Fax
Email
shahla.mirazizi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran blood transfusion center
Full name of responsible person
Dr Azarkeivan
Position
Hematologist
Other areas of specialty/work
Street address
Iran blood transfusion center-Hemmat highway-Tehran
City
Tehran
Postal code
Phone
+98 21 8860 1501
Fax
Email
azazarkeivan@gmail.comazazarkeivan@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Exir pharmacutical company
Full name of responsible person
Dr Jowzi
Position
Pharmacist
Other areas of specialty/work
Street address
N 22,rahmati alley,before Zartosht street,above valieasr sq
City
Postal code
Phone
00
Fax
Email
jozinarges@gmail.com
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