Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

To assess compliance, efficacy and satisfaction with two different formulation of deferasirox in patients with transfusion-dependent beta-thalassemia

Protocol summary

Summary

1- Objectives: to evaluate compliance, efficacy and safety of JADENU (new formulation of EXJADE) consumption among the transfusion dependent thalassemia major patients by designed questionnaire. 2- Design: the study is designed as a phase 3, open label, multicenter study. One hundred patients who eligible for inclusion criteria will be enrolled in the study. Fifty patients for JADENU and fifty patients for EXJADE consumption. 3- Setting and conduct: all stages of the project explain for each patient, then if they want to enter the project inform consent would be obtained. The patients will be treated by a 24 week Open label treatment phase. Serum Ferritin Levels will be measured monthly. 4- Participants including major eligibility criteria, transfusion dependent beta-thalassemia major patients. 5- Intervention, 20-40 mg/kg/day dose regimen of EXJADE and 14-28 mg/kg/day dose regimen of JADENU considering serum ferritin level. 6- Main outcome measures (variables), Include assessing the compliance, efficacy and safety of JADENU consumption. Serum Ferritin Levels will be measured monthly to evaluate the response to JADENU. The rate of satisfactions and compliance of patients in two groups of therapy will be evaluated at the end of study by designed questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101218603N2**
Registration date: **2015-12-21, 1394/09/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-12-21, 1394/09/30

Registrant information

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Fatemeh Amirmoezi
Name of organization / entity
Hematology research center/SUMS
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To assess compliance, efficacy and satisfaction with two different formulation of deferasirox in patients with transfusion-dependent beta-thalassemia

Public title

To assess compliance, efficacy and satisfaction with two different formulation of deferasirox in patients with transfusion-dependent beta-thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: signing informed consent; male or female aged ≥ 2 years at screening; patients with transfusion dependent thalassemia major; regular transfusion indicated by a blood requirement ≥ 8 blood transfusions per year at screening. Exclusion criteria: patients with mean levels of ALT above 5 fold the upper limit of normal (ULN); patients with serum creatinine above ULN; significant proteinuria as indicated by a urinary protein/creatinine ratio> 0.6 (mg/mg); creatinine clearance ≤ 60 ml/min; chronic hepatitis B infection; active hepatitis C infection; pregnancy or breastfeeding; non-transfusion dependent thalassemia (NTDT)

Age

From **10 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

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 Shiraz University of Medical Sciences

Street address

7th floor, Vice chancellery for research affairs, Shiraz University of Medical Sciences, Zand avenue, Shiaz, Iran

City

Shiraz

Postal code

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

IR.SUMS.REC.1394.152

Health conditions studied

1

Description of health condition studied

Major Thalassaemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

Patients compliance and satisfaction

Timepoint

three months after drug consumption

Method of measurement

designed questionnaire for patient compliance and satisfaction assessing

Secondary outcomes

1

Description

Ferritin serum amount

Timepoint

at the beginning of the study and monthly for 3 months

Method of measurement

Using starfax device

2

Description

Safety

Timepoint

Base line, End of evey month for 3 months

Method of measurement

Follow up, clinical examination by expert hematologist

3

Description

Possible gastrointestinal side effects, including diarrhea, and dermatologic symptoms

Timepoint

Base line, End of every month for three months

Method of measurement

Follow up,clinical examination by expert hematologist

Intervention groups

1

Description

Control group: 20-40 mg/kg/day dose regimen of EXJADE considering serum ferritin level. Frequency and route of administration is once per day orally. 20 mg/kg EXJADE (serum ferritin level: 1000- 1500), 30 mg/kg EXJADE

(serum ferritin level: 1500- 2000) and 40 mg/kg EXJADE (serum ferritin level ˃2000)

Category

Treatment - Drugs

2

Description

Intervention group: 14-28 mg/kg/day dose regimen of JADENU considering serum ferritin level. Frequency and route of administration is once per day orally. 14 mg/kg JADENU (serum ferritin level: 1000- 1500), 21 mg/kg JADENU (serum ferritin level: 1500- 2000) and 28 mg/kg JADENU (serum ferritin level ˃2000).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nemazee hospital, Shiaz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Dr. Mehran Karimi

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research, Shiaz Univeisity of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

7th floor, Shiraz University of Medical Sciences, Zand avenue, Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor of research, Shiaz Univeisity of Medical Sciences

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

Hematology Research Center, Nemazee Hospital, Shiraz, Iran

Full name of responsible person

Dr. Sezaneh Haghpanah

Position

Assistance professor of community medicine

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mehran Karimi

Position

Professor of Pediatric Hematology- Oncology

Other areas of specialty/work

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Person responsible for updating data

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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