Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

A comparison study of the effects of Jadenu®(Deferasirox) film-coated tablets and Exjade®(Deferasirox) tablets for oral suspension on reducing liver and heart iron overload in patients with Beta-Thalassemia Major and Intermedia

Protocol summary

Study aim

Comparison of the effect of Exjade® and Jadenu on the mean reduction of iron deposition in the heart and liver in patients with beta thalassemia major and intermedia

Design

he present study is a randomized controlled clinical trial in which patients will be randomly divided into two equal groups (n = 33). One group will be given Exjade® and the other group will be given Jadenu.

Settings and conduct

The present study is a randomized controlled clinical trial in which patients will be randomly divided into two equal groups (n = 33).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 2 years old patients with Beta-Thalassemia Major and Intermedia Serum ferritin above 1000 µg / mL Having informed consent to enter the study No entry conditions Having contraindication to Jadenu®and Exjade® Patients with GFR ˂40 mL / min / 1.73 m^2 Patients with stunted growth Patients with High-risk myelodysplastic syndromes (MDS) malignant cancer patients with platelet lower than 50x 10^9/L Patients with prior knowledge of allergy to drugs of the defrazirox group Patients with liver failure Patients with gastrointestinal bleeding Patients with renal failure Using other iron chelators at the same time age over 50 years old

Intervention groups

The control group receives Exjade and the intervention group receives Jadenu.

Main outcome variables

Cardiac iron load- Liver iron Load- Aspartate aminotransferase- Alanine transaminase-Existence of gastrointestinal side effects - level of satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210830052346N1**
Registration date: **2021-11-09, 1400/08/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-09, 1400/08/18**
Update count: **0**

Registration date

2021-11-09, 1400/08/18

Registrant information

Name
Mahya Mobinikhaledi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 86 3277 5382
Email address
mahya.mobini@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-09, 1400/08/18

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparison study of the effects of Jadenu®(Deferasirox) film-coated tablets and Exjade®(Deferasirox) tablets for oral suspension on reducing liver and heart iron overload in patients with Beta-Thalassemia Major and Intermedia

Public title
Effect of Jadenu®and Exjade®on reducing liver and heart iron overload in Beta-Thalassemia Major and Intermedia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 2 years old patients with Beta-Thalassemia Major and Intermedia Serum ferritin above 1000 µg / mL Having informed consent to enter the study

Exclusion criteria:
Having contraindication to Jadenu®and Exjade® Patients with GFR ˂40 mL / min / 1.73 m^2 Patients with stunted growth Patients with High-risk myelodysplastic syndromes (MDS) malignant cancer patients with platelet lower than 50x 10^9/L Patients with prior knowledge of allergy to drugs of the defrazirox group Patients with liver failure Patients with gastrointestinal bleeding Patients with renal failure Using other iron chelators at the same time age over 50 years old

Age
From **2 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Concealment is also guaranteed due to the use of permuted balanced block randomization method.

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 Arak University of Medical Sciences

Street address
No. 2, Sepahdar4, Sevom shaban st

City
Arak

Province
Markazi

Postal code
3815935139

Approval date
2020-11-29, 1399/09/09

Ethics committee reference number
IR.ARAKMU.REC.1399.250

Health conditions studied

1

Description of health condition studied
Beta Thalasemia major

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
cardiac iron load

Timepoint
At the beginning of the study and 6 months after taking Exjade or Jadenu

Method of measurement
T2*MRI

2

Description
liver iron load

Timepoint
At the beginning of the study and 6 months after taking Exjade or Jadenu

Method of measurement
T2*MRI

3

Description
Aspartate aminotransferase(AST)

Timepoint
At the beginning of the study and 2, 4 and 6 months after taking Exjade or Jadenu
Method of measurement
The patient's serum is separated by centrifugation and given to an autoanalyzer

4

Description
Alanine transaminase(ALT)
Timepoint
At the beginning of the study and 2, 4 and 6 months after taking Exjade or Jadenu
Method of measurement
The patient's serum is separated by centrifugation and given to an autoanalyzer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group that receives Jadenu. Jadenu is part of the drug class deferasirox . 33 people are being treated with Deferasirox (Jadenu®) for 6 months. This drug will be given as a swallowable tablet at a dose of 20 mg / kg per day (once a day, daily for 6 months, by Novartis Pharma AG, Basel, Switzerland) to patients in this group. we start the treatment with the dose of 20 mg / kg and increase the dose to 40 mg / kg if needed.
Category
Treatment - Drugs

2

Description
Control group: The group that receives Exjade. Exjade is part of the drug class deferasirox. 33 people are being treated with Exjade for 6 months. It is given as a granule tablet at a dose of 20 mg / kg per day (once a day, daily for six months, by Novartis Pharma AG, Basel, Switzerland). Start treatment with a dose of 20 mg / kg and increase the dose to 40 mg / kg if needed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir Hospital
Full name of responsible person
Vahid Falahati
Street address
Shahid Shirodi, Rahan st
City
Arak
Province
Markazi
Postal code
3819691187
Phone
+98 86 3313 5075
Email
mahya.mobini@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Amir Almasi
Street address
No2, Basij Square
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3313 6055
Email
modavem@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Vahid falahati
Position
Assistant professor
Latest degree

Subspecialist

Other areas of specialty/work
Pediatric Hematology & Oncologisy

Street address
No. 2, Sepahdar 4, Sevom Shaban st

City
Arak

Province
Markazi

Postal code
3815935139

Phone
+98 86 3277 5382

Email
mahya.mobini@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Vahid Falahati

Position
Assisstant professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatric Hematology and Oncology

Street address
No. 2, Sepahdar 4, Sevom Shaban st

City
Arak

Province
Markazi

Postal code
3815935139

Phone
+98 86 3277 5382

Email
mahya.mobini@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Vahid Falahati

Position
Assisstant professor

Latest degree
Subspecialist

Other areas of specialty/work
Others

Street address
No. 2, Sepahdar 4, Sevom Shaban st

City
Arak

Province
Markazi

Postal code
3815935139

Phone
+98 86 3277 5382

Email
mahya.mobini@yahoo.com

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
Due to the privacy of the information, patient information is kept confidential by the project manager

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available