Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison the effect deferasirox swallow form (Jadenu®) with deferasirox granule (Exjade®) in reduce of serum ferritin in patients with major and intermedia beta thalassemia

Protocol summary

Study aim

Comparison of the effect of swallowing defrazirox (Jadenu®) with granular form (Exjade®) in reducing serum ferritin levels in patients and its effect on Cr and BUN in patients with beta thalassemia major and intermedia

Design

The present study is a randomized controlled clinical trial with a parallel group without blinding 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 (33 people).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 2 years Patients diagnosed with thalassemia major and intermedia Having conscious satisfaction Serum ferritin above 1000 µg / mL Exclusion criteria: Existence of contraindications to the studied drugs (Exjade®) and(Jadenu®) Patients with GFR ˂40 mL / min / 1.73 m2; Patients with stunted growth Patients at high risk for myelodysplasia syndrome (MDS) Advanced cancer Platelets below 50 x 109 / L Patients with knowledge of sensitivity to drugs of the defrazirox group Patients with liver failure Patients with gastrointestinal bleeding Patients with renal insufficiency Simultaneous use of other iron chelators

Intervention groups

One group receives Exjade intervention and one group receives Jadenu intervention.

Main outcome variables

Serum ferritin level-Serum creatinine level-Blood urea nitrogen level-Presence of gastrointestinal side effects-Satisfaction rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210831052350N1**
Registration date: **2021-11-20, 1400/08/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-20, 1400/08/29**
Update count: **0**

Registration date

2021-11-20, 1400/08/29

Registrant information

Name

Fatemeh Zarei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3277 5382

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-15, 1400/08/24

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the effect deferasirox swallow form (Jadenu®) with deferasirox granule (Exjade®) in reduce of serum ferritin in patients with major and intermedia beta thalassemia

Public title
The effect of Jadenu with Exjade in reducing serum ferritin levels in patients with beta thalassemia major and intermedia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 2 years Patients diagnosed with thalassemia major and intermedia Having conscious satisfaction Serum ferritin above 1000 µg / mL

Exclusion criteria:
Existence of contraindications to the studied drugs (Exjade®) and (Jadenu®) Patients with GFR ˂40 mL / min / 1.73 m2 Patients with stunted growth Patients at high risk for myelodysplasia syndrome (MDS) Advanced cancer Platelets below 50 x 109 / L Patients with knowledge of sensitivity to drugs of the defrazirox group Patients with liver failure Patients with gastrointestinal bleeding Patients with renal insufficiency Simultaneous use of other iron chelators

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. 6, satarkhan,shahid shiroodi st

City
Arak

Province
Markazi

Postal code
3819765456

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

Ethics committee reference number
IR.ARAKMU.REC.1399.251

Health conditions studied

1

Description of health condition studied
major thalasemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

2

Description of health condition studied
intermedia thalasemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
serum ferritin

Timepoint
Sampling every two months

Method of measurement
The patient's serum is separated by centrifuge and given to an auto-analyzer

2

Description
Serum creatinine

Timepoint
Sampling every two months

Method of measurement
The patient's serum is separated by centrifuge and given to an auto-analyzer

3

Description
serum BUN
Timepoint
Sampling every two months
Method of measurement
The patient's serum is separated by centrifuge and given to an auto-analyzer

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:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir Hospital
Full name of responsible person
Vahid Falahati
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Shahid Shirodi Blvd,Rahahan st
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Amir Almasi
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No. 2,Basij Square
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3848176941
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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
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric Hematology and Oncology
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Person responsible for scientific inquiries

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Position
Associate professor

Latest degree
Subspecialist

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Person responsible for updating data

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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