# 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)

**Phone**

+98 86 3277 5382

**Email address**

fateme_zarei1995@yahoo.com

**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
**Street address**
Shahid Shirodi Blvd,Rahahan st
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fateme_zarei1995@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**
No. 2,Basij Square
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**Postal code**
3848176941
**Phone**
+98 86 3133 5506
**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**
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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## Person responsible for updating data

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Associate professor

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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