

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of Deferazirox and Deferoxamine on Serum Ferritin Levels Changes in Major Beta Thalassemia Patients

#### Protocol summary

2023-06-18, 1402/03/28

#### Study aim

Comparison of deferasirox and deferoxamine on serum ferritin level changes in beta thalassemia major patients

#### Design

Clinical trial, parallel groups, unblinded, randomized, 41 patients

#### Settings and conduct

The first group was treated with deferasirox (Nanoid) ± Defriprone (L1) and the second group was treated with deferoxamine (Desferal) ± Defriprone (L1). All patients received the drugs at a dose of 14 mg/kg and required blood tests including monthly CBC, ferritin and creatinine were checked for patients every three months. Finally, all statistical analysis was performed using software SPSS21.

#### Participants/Inclusion and exclusion criteria

The age of the patients was 2 years and older No gender restrictions Normal serum creatinine levels Absence of proteinuria in U/A patients

#### Intervention groups

The first group was treated with deferasirox (Nanoid) ± Defriprone(L1) and the second group was treated with deferoxamine (Desferal) ± Defriprone(L1).

#### Main outcome variables

serum ferritin level changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190817044550N4**

Registration date: **2023-06-18, 1402/03/28**

Registration timing: **retrospective**

Last update: **2023-06-18, 1402/03/28**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Mohammad Hoseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8950 2504

##### Email address

meditorha@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2022-10-23, 1401/08/01

#### Expected recruitment end date

2023-05-22, 1402/03/01

#### Actual recruitment start date

2022-10-23, 1401/08/01

#### Actual recruitment end date

2023-05-22, 1402/03/01

#### Trial completion date

2023-05-22, 1402/03/01

#### Scientific title

Comparison of Deferazirox and Deferoxamine on Serum Ferritin Levels Changes in Major Beta Thalassemia Patients

#### Public title

Comparison of Deferazirox and Deferoxamine on Serum Ferritin Levels Changes in Major Beta Thalassemia Patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The age of the patients was 2 years and older Have a

normal serum creatinine level Absence of proteinuria in U/A patients The serum ferritin levels of the patients should be above 1000 mg/dl, or the patients should have had more than 10 blood transfusions, or the volume of blood transferred should be more than 100 cc/kg

**Exclusion criteria:**

Pregnancy and breastfeeding Resistant levels greater than 5 times the normal value of liver transaminase Severe nausea and vomiting in the patient Patient refusal to participate in the study

**Age**

From **2 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

Actual sample size reached: **41**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We used the permuted block randomization method, and these blocks were randomly designed in Excel software, and then groups equal to the allocation of a as the intervention group and b as the control group were performed.

**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 Birjand University of Medical Sciences

**Street address**

Birjand University of Medical Sciences, Ghaffari Street

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Approval date**

2022-10-10, 1401/07/18

**Ethics committee reference number**

IR.BUMS.REC.1401.263

**Health conditions studied**

1

**Description of health condition studied**

beta thalassemia major

**ICD-10 code**

D56.1

**ICD-10 code description**

Beta thalassemia

**Primary outcomes**

1

**Description**

Serum ferritin level

**Timepoint**

Measurement of serum ferritin level at the beginning of the study (before the start of the intervention), 3 and 6 months after the start of the intervention

**Method of measurement**

Biochemical test

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Treated with deferasirox (Nan jade) ± Deferiprone

**Category**

Treatment - Drugs

2

**Description**

Intervention group: Treated with deferoxamine (Desferal) ± deferiprone

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Birjand University of Medical Sciences

**Full name of responsible person**

Tayyebah Chahkandi

**Street address**

Faculty of Medicine, Birjand University of Medical Sciences, Birjand

**City**

Birjand

**Province**

South Khorasan

**Postal code**  
9717853577  
**Phone**  
+98 56 3162 2001  
**Email**  
na\_chahkandi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Tayyebeh Chahkandi  
**Street address**  
Ghaffari street, Birjand University of Medical Sciences,  
Birjand  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717853577  
**Phone**  
+98 56 3162 2001  
**Email**  
na\_chahkandi@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Birjand 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**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Saeedeh Khorashadi zadeh  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Hematology  
**Street address**

Ghaffari St., Birjand University of Medical Sciences  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717853577  
**Phone**  
+98 56 3162 2001  
**Email**  
saedehkhorashadi4590@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Tayyebeh Chahkandi  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Ghaffari St., Birjand University of Medical Sciences  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717853577  
**Phone**  
+98 56 3162 2001  
**Email**  
na\_chahkandi@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Saeedeh Khorashadi zadeh  
**Position**  
resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Hematology  
**Street address**  
Ghaffari St., Birjand University of Medical Sciences  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717853577  
**Phone**  
+98 56 3162 2001

**Email**

skhorashadi4590@gmail.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**

The data obtained from this project will eventually be reported as standard and general, and reporting personal information by individuals does not seem necessary.

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Demographic information and information about the main outcome of this project can be shared.

**When the data will become available and for how long**

Start of access period 1 year after printing the results

**To whom data/document is available**

The data of this project can be shared by all aspiring researchers working in academic and scientific institutes.

**Under which criteria data/document could be used**

Appropriate scientific use of the data of this study in order to improve the quality of similar studies is unimpeded.

**From where data/document is obtainable**

The data of the present research is possible by announcing the request via email khorashadi4590@gmail.com and also na\_chahkandi@yahoo.com.

**What processes are involved for a request to access data/document**

After confirming the eligibility of the person requesting the information, the data will be sent as soon as possible via the above emails.

**Comments**