

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Combined Therapy with Deferoxamine and Deferiprone versus Monotherapy with Deferoxamine or Deferiprone in Iron Overloaded Thalassemia Patients

#### Protocol summary

##### Summary

(1) Objective: The aim of this study was to compare Desferrioxamine (DFO) and Deferiprone (DFP) alone with a combined therapy with DFO and DFP in beta thalassemia major patients with iron overload. (2) Design: This study is a single blind randomized controlled clinical trial. (3) Setting and conduct: This study was done at Ormieh Motahari hospital. Eligible subjects were randomized to receive one of the following treatments; DFO alone DFP alone and DFP combination with DFO. (4) Participants including major eligibility criteria: This clinical trial was carrying out on 36 patients with thalassemia major of both sex and aged more than three years. (5) Intervention: Thirty six patients with thalassemia major were randomized to three groups and receive one of the following two treatments; 12 patients treated with DFO alone (50 mg/kg, 5 days weekly), 12 patients treated with DFP alone (75 mg/kg, daily) and 12 patients treated with DFP given at a daily dose of 75 mg/kg in combination with DFO (50 mg/kg, twice weekly). All patients received regular blood transfusions at 2-4 weekly intervals to maintain hemoglobin levels above 9 g/dL and all had been treated with DFO prior to the commencement of the study. (6) Main outcome measures: Serum ferritin concentrations were measured at two monthly intervals prospectively to assess the efficacy of therapy. Full blood count was performed at each monthly visit, while liver and renal function assessment was performed at three monthly intervals.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041627412N1**

Registration date: **2016-05-04, 1395/02/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-04, 1395/02/15

##### Registrant information

###### Name

Mostafa Qorbani

###### Name of organization / entity

Alborz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3281 9277

###### Email address

mqorbani1379@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Urmia University of Medical Sciences

##### Expected recruitment start date

2012-04-20, 1391/02/01

##### Expected recruitment end date

2012-08-22, 1391/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Combined Therapy with Deferoxamine and Deferiprone versus Monotherapy with Deferoxamine or Deferiprone in Iron Overloaded Thalassemia Patients

##### Public title

Treatment of iron overload in thalassemia patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion Criteria: Transfusion-dependent Thalassemia; Age more than three years; Serum ferritin level > 5,000 ng/L and progressively increasing undergoing chelating therapy with subcutaneous DFO Exclusion Criteria: Severe liver, kidney or cardiac disease; Serious adverse events with DFO or DFP; Neutrophil count < 2000/L during the past 2 years; Platelet count < 100,000/L; History of arthropathy

**Age**

From **3 years** old to **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single 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 Urmia University of Medical Sciences

**Street address**

Urmia University of Medical Sciences, Resalat Boulevard, Karaj

**City**

Urmia

**Postal code**

5714783734

**Approval date**

2010-05-18, 1389/02/28

**Ethics committee reference number**

5589

**Health conditions studied****1****Description of health condition studied**

Thalassemia

**ICD-10 code**

D56.1

**ICD-10 code description**

Beta thalassaemia

**Primary outcomes****1****Description**

serum ferritin

**Timepoint**

before intervention and in 2, 4, 6, 8, 10 and 12 month intervals after intervention

**Method of measurement**

ng/mL

**Secondary outcomes****1****Description**

complete blood count

**Timepoint**

before intervention and monthly for 12 month after intervention

**Method of measurement**

blood examination

**Intervention groups****1****Description**

Intervention group 2: patients treated with DFP alone (75 mg/kg, daily)

**Category**

Treatment - Drugs

**2****Description**

Control group: patients treated with DFO alone (50 mg/kg, 5 days weekly)

**Category**

Treatment - Drugs

**3****Description**

Intervention group 1: patients treated with DFP given at a daily dose of 75 mg/kg in combination with DFO (50 mg/kg, twice weekly)

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Motahari Hospital

**Full name of responsible person**

Omid Safari

**Street address**

Shahid Motahari Hospital, Kashani Street, Urmia, Iran

**City**

Urmia

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Urmia University of Medical Sciences

**Full name of responsible person**

Firooz Ghaderi

**Street address**

Urmia University of Medical Sciences, Resalat Boulevard, Urmia, Iran.

**City**

Urmia

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Urmia University 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**

Alborz University of Medical Sciences

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Mostafa Qorbani

**Position**

Doctor of Philosophy in Epidemiology/assistant professor

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## Person responsible for scientific inquiries

#### Contact

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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*