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

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Name of organization / entity
Alborz University of Medical Sciences
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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; Neutriphil 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
Śhahid Motahari Hospital
Full name of responsible person
Omid Safari
Street address
Śhahid 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
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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