

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Oral versus Injectable Iron Chelation Therapy in Reducing Serum Ferritin Levels in Patients with Transfusion Dependent Thalassemia

#### Protocol summary

##### Study aim

To compare the mean serum ferritin level with oral versus injectable iron chelation therapy in patients with transfusion dependent thalassemia.

##### Design

A single center, open-labelled, randomized controlled trial. Children in the intervention group will be given oral iron chelation therapy i.e. daily Deferiprone at a dose of 75mg/kg/day in two to three divided doses for a period of 6-months. In the control group, children will be given injectable iron chelation therapy i.e. single dose of deferoxamine 4 mmol, 6 days a week for a duration of 6-months. Sample size will be 50 children (25 in each group) as per inclusion and exclusion criteria.

##### Settings and conduct

This open labelled trial will be conducted at The Department of Pediatric Medicine, DHQ Teaching Hospital, Dera Ghazi Khan, Pakistan

##### Participants/Inclusion and exclusion criteria

Inclusion criteria will be children of both genders and age >1 up to 15 years presenting with beta thalassemia major. Exclusion criteria will be children already taking trial treatment, or liver failure (ALT & AST >50IU), anemia (hemoglobin level <10 g/dl) or those who will lose during the follow ups.

##### Intervention groups

In the intervention group will be given oral iron chelation therapy i.e. daily Deferiprone at a dose of 75mg/kg/day in two to three divided doses for a period of 6-months. Control group: Children will be given injectable iron chelation therapy i.e. single dose of deferoxamine 4 mmol (225 mg) daily, 6-days a week, for a period of 6-months.

##### Main outcome variables

Serum ferritin will be assessed at baseline and after 6 months of therapy in terms of ng/ml and change in serum ferritin level will be calculated as difference in

serum ferritin level obtained at two follow-up visits.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221231056999N2**

Registration date: **2023-07-25, 1402/05/03**

Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**

Update count: **0**

##### Registration date

2023-07-25, 1402/05/03

##### Registrant information

##### Name

M Aamir

##### Name of organization / entity

RESnTEC, Institute of Research

##### Country

Pakistan

##### Phone

+92 321 6801143

##### Email address

aamir@resntec.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-01, 1402/05/10

##### Expected recruitment end date

2024-02-28, 1402/12/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of Oral versus Injectable Iron Chelation Therapy in Reducing Serum Ferritin Levels in Patients with Transfusion Dependent Thalassemia

**Public title**  
Comparison of Oral versus Injectable Iron Chelation Therapy in Reducing Serum Ferritin Levels in Patients with Transfusion Dependent Thalassemia

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Presenting with beta thalassemia major (defined as group of hereditary disorders characterized by a genetic deficiency in the synthesis of beta-globin chains in blood causes severe, transfusion-dependent anemia). Patients who are transfusions dependent with serum ferritin level >2000 ng/ml.  
**Exclusion criteria:**  
Children already taking trial treatment (as per medical record). Children with liver failure (ALT & AST >50IU). Children having anemia (hemoglobin level <10 g/dl) Children who will lose during follow ups. Parents/Guardian refused the participation of their child. Stoppage of medicine due to side effects/compliance.

**Age**  
From **1 year** old to **15 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Children will be randomly divided in two groups by using random number table that will be generated by using Microsoft Excel

**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**  
Institutional Ethical Committee  
**Street address**  
Jampur Road  
**City**  
Dera Ghazi Khan  
**Postal code**  
32200  
**Approval date**  
2023-04-20, 1402/01/31  
**Ethics committee reference number**  
45-IEC-2032

**Health conditions studied**

1

**Description of health condition studied**  
Beta thalassemia  
**ICD-10 code**  
D56.1  
**ICD-10 code description**  
Beta thalassemia

**Primary outcomes**

1

**Description**  
Serum ferritin level  
**Timepoint**  
Assessed at baseline and after 6 months of therapy  
**Method of measurement**  
Blood sample will be taken by using 3cc disposable syringe and sent to the laboratory of the hospital for assessment of serum ferritin level using standard laboratory protocols.

**Secondary outcomes**  
empty

**Intervention groups**

1

**Description**  
Intervention group: Children will be given oral iron chelation therapy i.e. daily Deferiprone at a dose of 75mg/kg/day in two to three divided doses, for a period of 6-months.  
**Category**  
Treatment - Drugs

2

**Description**  
Control group: Children will be given injectable iron chelation therapy i.e. single dose of deferoxamine 4

mmol (225 mg) daily, 6-days a week, for a period of 6-months.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Department of Pediatric Medicine, DHQ Teaching Hospital, Dera Ghazi Khan

**Full name of responsible person**

Dr. Fatima Rafique

**Street address**

Jampur Road

**City**

Dera Ghazi Khan

**Postal code**

32200

**Phone**

+92 335 0999989

**Email**

aamir@resntec.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

DHQ Teaching Hospital

**Full name of responsible person**

Dr. Fatima Rafique

**Street address**

Jampur Road

**City**

Dera Ghazi Khan

**Postal code**

32200

**Phone**

+92 335 0999989

**Email**

aamir@resntec.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

None

**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**

RESnTEC, Institute of Research

**Full name of responsible person**

M. Aamir

**Position**

Research Consultant

**Latest degree**

Bachelor

**Other areas of specialty/work**

Research Consultation

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**Contact**

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**Position**

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**Latest degree**

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**Position**

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**Latest degree**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

Undecided - It is not yet known if there will be 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**

No - There is not 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**

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

**Data Dictionary**

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