

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### A comparative study on the effectiveness and complications of Desferal and Desphonac in thalassemic patients in Kermanshah 2018-2019

#### Protocol summary

##### Study aim

A comparative study on the effectiveness and complications of Desferal and Desphonac in thalassemic patients

##### Design

This study is a one-blinded clinical trial. The study population will be included of all patients that receive iron chelator and referred to thalassemia department Mohammad Kermanshahi hospital. A total of 98 eligible patients will be selected conveniently and randomly will be assigned to two intervention groups.

##### Settings and conduct

This study which will be conducted in Mohammad Kermanshahi hospital is one-blinded one that participants do not know what drug they will receive. At the beginning of the study, renal, hepatic, ferritin and iron tests will be performed in both groups and the data will be recorded in a checklist.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with thalassemia intermedia and thalassemia major  
Exclusion criteria: Patients with hypertension, skin diseases, liver complications, and respiratory and auditory diseases

##### Intervention groups

The second intervention group will receive desferal for 8 consecutive days in the weekend for five consecutive days through the pump. The first intervention group will receive desferal for 8 consecutive days in the weekend for five consecutive days through the pump

##### Main outcome variables

Respiratory status; Digestive complications; Skin complications; Kidney and liver complications

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N117**

Registration date: **2019-03-17, 1397/12/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-17, 1397/12/26**

Update count: **0**

##### Registration date

2019-03-17, 1397/12/26

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-11, 1397/12/20

##### Expected recruitment end date

2019-06-10, 1398/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study on the effectiveness and complications of Desferal and Desphonac in thalassemic patients in Kermanshah 2018-2019

##### Public title

Comparison of the effectiveness and complications of Desferal and Desphonac in thalassemic patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with intermedia and major thalassemia

### Exclusion criteria:

Renal patients Patients with hypertension, skin diseases, liver complications, and respiratory and auditory diseases

## Age

From **15 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **98**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Individually randomization by random number table via code receipt

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, patients will be blinded to the study groups, dosage of the drug and the manufacturer of the drug

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

#### Approval date

2019-01-30, 1397/11/10

## Ethics committee reference number

ir.kums.rec.1397.930

## Health conditions studied

### 1

#### Description of health condition studied

Thalassemia

#### ICD-10 code

D56.1

#### ICD-10 code description

Beta thalassemia

## Primary outcomes

### 1

#### Description

respiratory status

#### Timepoint

Beginning of the study and end of the study (three months later)

#### Method of measurement

According to clinical symptoms and asking patients

### 2

#### Description

Digestive complications

#### Timepoint

Beginning of the study and end of the study (three months later)

#### Method of measurement

According to symptoms and asking patients

### 3

#### Description

Skin complications

#### Timepoint

Beginning of the study and end of the study (three months later)

#### Method of measurement

According to clinical symptoms and asking patients

### 4

#### Description

Renal and hepatic complications

#### Timepoint

Beginning of the study and end of the study (three months later)

#### Method of measurement

blood test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group will receive desferal for 8 consecutive days in the weekend for five consecutive days through the pump

#### Category

Treatment - Drugs

### 2

#### Description

The second intervention group will receive desferal for 8 consecutive days in the weekend for five consecutive days through the pump

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mohammad Kermanshahi Hospital

##### Full name of responsible person

Dr. Nargece Soraya

##### Street address

Intersection Helal Ahmar

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6713733135

##### Phone

+98 83 3721 8202

##### Email

nargece.soraya@kums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Farid Najafi

##### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3836 0014

##### Email

fnajafi@kums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Nargece Soraya

##### Position

Resident of children

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Pediatrics

##### Street address

Intersection Helal Ahmar

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6713733135

##### Phone

+98 83 3721 8202

##### Email

nargece.soraya@kums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. MohammadReza Golpayegani

##### Position

Faculty Member of Kermanshah University of Medical Sciences

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Hematology

**Street address**

Intersection Helal Ahmar

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**Province**

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**Email**

mrgolpayegani@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Nargece Soraya

**Position**

Resident of children

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Intersection Helal Ahmar

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6713733135

**Phone**

+98 83 3721 8202

**Email**

nargece.soraya@kums.ac.ir

**Sharing plan**

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

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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**

Not applicable

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

The main outcomes of the study will be shared.

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

6 months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

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

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

**Comments**