Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 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)

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+98 83 1821 4653

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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
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6713733135
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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
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Postal code
6715847141
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+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
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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

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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

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Dr. Nargece Soraya

Position
Resident of children

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Email
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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