Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of blood transfusion intervals in patients with β-thalassemia major before and after administration of hydroxyurea

Protocol summary

Study aim
Determination of blood transfusion intervals in patients with β-thalassemia major before and after administration of hydroxyurea in patients referred to Taleghani Hospital in Gorgan, 2017-2018

Design
Clinical trials without community-based control, analytical and functional, with a sample size of 20 people

Settings and conduct
The location of the study is Taleghani Children Hospital in Gorgan, Oral Medicine is administered orally to patients, regular and monthly blood tests, and liver tests every 3 months.

Participants/Inclusion and exclusion criteria
All patients are β-thalassemia major who have been treated with blood transfusion, and after approval of the plan, they are treated monthly with hydroxyurea for 6 months. Exit Conditions: occurrence of any severe hematologic ,renal ,hepatic and skin disease

Intervention groups
Major thalassemia patients with a maximum age of 18 years who have already been treated with regular blood transfusions and received a hydroxyurea after 6 months of approval.

Main outcome variables
Increased hemoglobin total levels, changes in liver enzymes levels, reduced complications from blood transfusion, reduced treatment costs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180707040371N1**
Registration date: **2018-12-15, 1397/09/24**
Registration timing: **retrospective**
Last update: **2018-12-15, 1397/09/24**
Update count: **0**

Registration date
2018-12-15, 1397/09/24

Registrant information

Name
Sohail Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 17 3358 9501

Email address
soheilgh1992@goums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-11, 1396/06/20

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
2017-09-27, 1396/07/05

Actual recruitment end date
2018-10-27, 1397/08/05

Trial completion date
empty

Scientific title
Evaluation of blood transfusion intervals in patients with β-thalassemia major before and after administration of hydroxyurea

Public title
Evaluation of blood transfusion intervals in patients with β-thalassemia major before and after administration of hydroxyurea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients are β-thalassemia major who have been treated with blood transfusion, and after approval of the plan, they are treated monthly with hydroxyurea for 6 months.

Exclusion criteria:

Patients who do not tend to take oral medications
Patients with unstable hemodynamic status

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**
Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Educational Complex of the Falsafi, First Road of 60kola, km 4 of Gorgan Sari road, Gorgan, Golestan Province, Iran

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2017-09-03, 1396/06/12

Ethics committee reference number

IR.GOUMS.REC.1396.287

Health conditions studied

1

Description of health condition studied

Beta-thalassemia Major disease

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Blood transfusion intervals in patients

Timepoint

Frequency of blood transfusion in patients at baseline and then monthly for 6 months after administration of hydroxyurea

Method of measurement

cell blood count-patient files

2

Description

Hemoglobin total measurement

Timepoint

Hemoglobin total measurements at baseline and then monthly for 6 months after administration of hydroxyurea

Method of measurement

CBC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: hydroxy urea capsule (500 mg capsules)made by Apotex Canada with a dose of 20to30mg / kg for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Medical and Educational Center in Gorgan - Thalassemia and Oncology Department

Full name of responsible person

Narges Beygum Mirbehbahani

Street address

Janbazan Blvd, Azadi street, Gogan city, Golestan Province, Iran

City

Gorgan
Province
Golestan
Postal code
4916668197
Phone
+98 17 3222 7720
Email
taleghanihospital@goums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Mohamad Reza Honarvar
Street address
Educational Complex of the Falsafi, Begining of the Road of 60kola, km 4 of Gorgan Sari road, Golestan Province, Iran
City
gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3245 1660
Email
info@goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Narges Beigom Mirbehbahani
Position
Assistant Professor of Pediatrics
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Janbazan Blvd, Azadi Street, Gorgan City, Iran
City
Gorgan
Province
Golestan
Postal code
4917946877
Phone
+98 17 3232 8539
Email
www.mirbeh@goums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Narges Beigom Mirbehbahani
Position
Assistant Professor, Department of Pediatrics, Pediatric Hematology and Pediatric Oncology, Ph.D.
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Janbazan Blvd,Azadi Street , Gorgan City
City
Gorgan
Province
Golestan
Postal code
4917946877
Phone
+98 17 3232 8539
Email
www.mirbeh@goums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Narges Beigom Mirbehbahani
Position
Assistant Professor, Department of Pediatrics, Pediatric Hematology and Pediatric Oncology, Ph.D.
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Janbazan Blvd,Azadi Street , Gorgan City
City
Gorgan

Province
Golestan
Postal code
4917946877
Phone
+98 17 3232 8539
Email
www.mirbeh@goums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because the hospital information file is kept at the documentation center and is in some way confidential and non-existent
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
There is no possibility to publish all the information, but information about the outcome of the study will be published
When the data will become available and for how long
Information is available up to one year after the date of printing
To whom data/document is available
Data is only available for academic researchers
Under which criteria data/document could be used
The decision is based on the opinion of the university's research center and the relevant academic rules
From where data/document is obtainable
For information about research please go to Cancer Research Center at Sayyad Shirazi Hospital Hospital Address: Sayyad Shirazi Blvd., Sayyad Shirazi Hospital website of GOUMS university:www.goums.ac.ir
What processes are involved for a request to access data/document
It takes about a week
Comments