

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation of blood transfusion intervals in patients with $\beta$ -thalassemia major before and after administration of hydroxyurea

#### Protocol summary

##### Study aim

Determination of blood transfusion intervals in patients with  $\beta$ -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  $\beta$ -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  $\beta$ -thalassemia major before and after administration of hydroxyurea

##### Public title

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

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All patients are  $\beta$ -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**  
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**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**  
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## 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**  
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**Street address**  
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**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**