

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of the efficacy and safety of herbal product (Resveratrol) with Hydroxyurea (HU) in non- transfusion- dependent B-thalassemia-intermedia

#### Protocol summary

##### Summary

Objective: the aim of this study was evaluation and comparison of the efficacy and safety of herbal product (Resveratrol) with HU in non- transfusion- dependent B-thalassemia-intermedia. Inclusion criteria: non transfused in the 6 months ago; patients who did not receive HbF- inducer in the 6 months ago; normal liver or kidney function tests; normal CBC test. Exclusion criteria: Patients will be excluded from this trial if they have one of the following criteria: Abnormal liver or kidney function tests; An alanine aminotranferase (ALT) level and aspartate aminotransferase (AST) greater than 3 fold; serum creatinine level above the upper limit of normal; they can leave the study when they want. Target sample size was sixty. Intervention studied was Resveratrol 1 gr/day orally, Hydroxyurea 10-15(mg/kg/day). Variation in Hb, HbF (every month for 6 months) and need to transfusion was evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014112320051N2**  
Registration date: **2015-08-19, 1394/05/28**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-08-19, 1394/05/28

##### Registrant information

##### Name

Mehran Karimi

##### Name of organization / entity

Hematology Research Center, Shiraz University of

Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3612 5617

##### Email address

karimim@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2015-10-23, 1394/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy and safety of herbal product (Resveratrol) with Hydroxyurea (HU) in non- transfusion- dependent B-thalassemia-intermedia

##### Public title

Evaluation and comparison of the efficacy and safety of Resveratrol with Hydroxyurea (HU) in B-thalassemia-intermedia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: non transfused in the 6 months ago; patients who did not receive HbF- inducer in the 6 months ago; normal liver or kidney function tests; normal

CBC test. Exclusion criteria: Patients will be excluded from this trial if they have one of the following criteria: Abnormal liver or kidney function tests; An alanine aminotransferase (ALT) level and aspartate aminotransferase (AST) greater than 3 fold; serum creatinine level above the upper limit of normal; they can leave the study when they want

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: 60

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

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

Convenience sampling randomization was done using block randomization

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethic Committee of Shiraz University of Medical Sciences

##### **Street address**

Shiraz University of Medical Sciences, Zand Street, Shiraz

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2015-04-19, 1394/01/30

#### **Ethics committee reference number**

IR.SUMS.REC.1394.16

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Thalassemia

#### **ICD-10 code**

D56.1

#### **ICD-10 code description**

Thalassemia Intermedia

## **Primary outcomes**

### **1**

#### **Description**

1:HB

#### **Timepoint**

Base line,End of every month,End of study

#### **Method of measurement**

CBC

### **2**

#### **Description**

2: HbF

#### **Timepoint**

base line,End of every month,End of study

#### **Method of measurement**

Hemoglobin Electrophoresis

## **Secondary outcomes**

### **1**

#### **Description**

1:Saftey

#### **Timepoint**

Base line,End of every month,end of study

#### **Method of measurement**

Follow up,clinical examination by expert hematologist

### **2**

#### **Description**

2:Possible gastrointestinal side effects ,including diarrhea

#### **Timepoint**

Base line,End of every month,End of study

#### **Method of measurement**

Follow up,clinical examination by expert hematologist

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: patients treated with HU, Resveratrol Resveratrol 1 gr/day orally, Hydroxyurea 10-15(mg/kg/day)

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: including Placebo + Hydroxyurea 10-15 mg/kg/day

#### **Category**

Placebo

### 3

#### Description

Intervention group 2: including Resveratrol 1 gr/day orally + Placebo

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Hematology Research Center

###### Full name of responsible person

Mozhgan Rezaei

###### Street address

Hematology Research Center, Nemazee Hospital, Zand street, Shiraz

###### City

Shiraz

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

###### Full name of responsible person

Mehran Karimi

###### Street address

Hematology Research Center, Nemazee Hospital, Zand Street

###### City

Shiraz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

### Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Hematology Research Center, Nemazee Hospital, Shiraz

##### Full name of responsible person

Sezaneh Haghpanah

##### Position

Assistance professor of community medicine

##### Other areas of specialty/work

##### Street address

Hematology Research Center, Nemazee Hospital, Zand Street, Shiraz

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### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mehran Karimi

##### Position

Professor of Pediatric Hematology-Oncology  
Hematology Research Center

##### Other areas of specialty/work

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### Person responsible for updating data

#### Contact

##### Name of organization / entity

Hematology Research Center, Nemazee Hospital, Shiraz

##### Full name of responsible person

Tahereh Zarei

##### Position

Msc Microbiologist

##### Other areas of specialty/work

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*