

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the Effects of Thalidomide on Hemoglobin Levels in Patients with Thalassemia Intermedia: A Clinical trial

#### Protocol summary

##### Study aim

To evaluate the effect of thalidomide on hemoglobin levels in patients with thalassemia intermedia who are dependent on blood transfusions and have not responded favorably to hydroxyurea treatment

##### Design

The study includes only an intervention group. No blinding is applied. Conducted in Phase 2. Performed on 50 patients. Randomization is not required.

##### Settings and conduct

This is a single-center and interventional study. Conducted at Shahid Baghaei 2 Hospital. Patients meeting the inclusion criteria will receive thalidomide and aspirin after visiting the medical center. Patient follow-ups will be conducted at regular intervals over an 8-week period.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Visiting the Baghaei 2 Medical Center and having a medical record there Dependency on blood transfusions Lack of a favorable response to hydroxyurea treatment Age over 18 years Baseline hemoglobin level of less than 10 Signing the informed consent form  
Exclusion Criteria: History of hypersensitivity reaction to thalidomide Pregnancy or breastfeeding

##### Intervention groups

Patients with thalassemia intermedia who visit the Shahid Baghaei 2 Hospital Medical Center.

##### Main outcome variables

Change in hemoglobin levels before and after the intervention (at the end of 8 weeks) Blood transfusion requirement before and after the intervention Adverse effects related to thalidomide use

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180603039959N5**

Registration date: **2025-02-15, 1403/11/27**

Registration timing: **prospective**

Last update: **2025-02-15, 1403/11/27**

Update count: **0**

##### Registration date

2025-02-15, 1403/11/27

##### Registrant information

###### Name

bijan keikhaei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3375 0410

###### Email address

keikhaeib@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-02-28, 1403/12/10

##### Expected recruitment end date

2025-05-31, 1404/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Effects of Thalidomide on Hemoglobin Levels in Patients with Thalassemia Intermedia: A Clinical trial

##### Public title

Thalidomide in Thalassemia Intermedia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Visiting the Baghaei 2 Medical Center and having a medical record there  
Dependency on blood transfusions  
Lack of a favorable response to hydroxyurea treatment  
Age over 18 years  
Baseline hemoglobin level of less than 10  
Signing the informed consent form

### Exclusion criteria:

History of hypersensitivity reaction to thalidomide  
Pregnancy or breastfeeding

## Age

From **18 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## 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

کارگروه/ کمیته اخلاق در پژوهش دانشگاه علوم پزشکی جندی  
شاپور اهواز

##### Street address

Farvardin Blvd, Golestan region

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6138933333

#### Approval date

2025-01-18, 1403/10/29

#### Ethics committee reference number

IR.AJUMS.REC.1403.560

## Health conditions studied

### 1

#### Description of health condition studied

thalassemia intermedia

#### ICD-10 code

D56.1

#### ICD-10 code description

Beta thalassemia

## Primary outcomes

### 1

#### Description

Hemoglobin

#### Timepoint

Before starting the medication and at the end of 8 weeks

#### Method of measurement

Hemoglobin level will be measured using a complete blood count (CBC) test with a hematology analyzer.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group:

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Baghaei 2 Hospital

##### Full name of responsible person

Bijan Keikhaei Dehdezi

##### Street address

Golestan BLV

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6135715794

##### Phone

+98 61 3375 0410

##### Email

keikhaeib@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

**Full name of responsible person**

عبدالله رفيعى

**Street address**

Golestan blvd

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3373 8383

**Fax**

+98 61 3373 8294

**Email**

itc@ajums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Daryush Purrahrman

**Position**

research asistant

**Latest degree**

Master

**Other areas of specialty/work**

Hematology

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Daryush Purrahrman

**Position**

Research assistant

**Latest degree**

Master

**Other areas of specialty/work**

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Daryush Purrahrman

**Position**

Research assistant

**Latest degree**

Master

**Other areas of specialty/work**

Hematology

**Street address**

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**City**

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**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3375 0410

**Fax**

**Email**

daryushpurrahrman@gmail.com

**Web page address**

**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**

Due to concerns regarding patient privacy and ethical considerations, individual patient data (IPD) will not be shared. Additionally, data sharing may require legal permissions and compliance with data protection regulations.

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available