

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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Khouzestan

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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 رفيعی

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+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

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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