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
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Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3375 0410
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keikhaeib@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

عبدالله رفیعی

Street address

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Khouzestan

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+98 61 3373 8383

Fax

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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 Purrahman

Position

research asistant

Latest degree

Master

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

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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