

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Role of hemoglobin and the effect of it's correction on pregnancy outcome in minor and intermedia thalassemia patients

Protocol summary

2016-02-18, 1394/11/29

Summary

This study is a prospective and randomized single-blind clinical trial. The aim of this study is role of hemoglobin and the effect of it's correction on pregnancy outcome in minor and intermedia thalassemia patients. Total of sample size is 36 patient with ages: 20-35 years old. Inclusion criteria are thalassemia minor and intermedia women and pregnant With hemoglobin over 8.5. The patients with metabolic diseases such as cushing syndrome and chronic diseases such as rheumatic disease and age over 35 years will be excluded. The patients are randomly divided into two groups by blocked randomization. Assessor of study do not know about grouping patients. This study is 3 trial phase. First group receives One or several packed cells (Bag of packed red blood cells) based on hemoglobin of body. The second group as a control group does not receive anything. Both groups receives pharmaceutical plan such as folic acid and ferrous sulfate according to hematologists. Hemoglobin all patients and fetal health status is checked once every two weeks. Patients information such as age, BMI, spontaneous abortion and stillbirth, oligohydramnios, fetal anomalies, SGA, LBW, VLBW, baby delivery method, preterm delivery, the number of packet cell will be recorded in both groups during pregnancy and after baby delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010825903N1**

Registration date: **2016-02-18, 1394/11/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Mahin Bahadori

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3222 2922

Email address

bahadori.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-01-25, 1394/11/05

Expected recruitment end date

2016-07-26, 1395/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of hemoglobin and the effect of it's correction on pregnancy outcome in minor and intermedia thalassemia patients

Public title

Evaluation of hemoglobin in pregnant women with thalassemia minor and intermedia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: thalassaemia minor and intermedia women and pregnant With hemoglobin over 8.5; Bearing a singleton baby; Patient with ages: 20-35 years old.
Exclusion Criteria: Patients with metabolic diseases such as cushing syndrome, Hypothyroidism and hyperthyroidism; chronic diseases such as rheumatic disease, autoimmune and antiphospholipid syndrome.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University Of
Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur
University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.AJUMS.REC.1394.562

Health conditions studied

1

Description of health condition studied

thalassaemia

ICD-10 code

D56.1

ICD-10 code description

Cooley anaemia, Severe beta thalassaemia,
Thalassaemia: Intermedia, major

2

Description of health condition studied

Pregnancy

ICD-10 code

O00-O99

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Stillbirth

Timepoint

Once each month, during pregnancy

Method of measurement

Patient appointments

2

Description

spontaneous abortion

Timepoint

Once each month, during pregnancy

Method of measurement

Patient appointments

3

Description

The amount of hemoglobin

Timepoint

Before intervention and once each month

Method of measurement

Venous sampling and sent to the laboratory

4

Description

oligohydramnios

Timepoint

Once each month, during pregnancy

Method of measurement

sonography

5

Description

Fetal anomaly

Timepoint

Once each month, during pregnancy

Method of measurement

sonography

6

Description

baby delivery method

Timepoint

during baby delivery

Method of measurement

Patient appointments and record baby's birth

7

Description

SGA (small for gestational age)

Timepoint

Once each month, during pregnancy

Method of measurement

sonography

8

Description

VLBW (Very low birth weight)

Timepoint

during baby delivery

Method of measurement

Patient appointments and record uterine contractions

9

Description

The number of pack cell required for injection

Timepoint

Once each month, during pregnancy

Method of measurement

Patient appointments and record

Secondary outcomes

1

Description

Blood transfusion complication (nausea, vomiting, fever and chills)

Timepoint

During the transfusion and 2 hours after blood transfusion

Method of measurement

Oral questionnaire and patient response

Intervention groups

1

Description

Intervention group: Prescription One or several packed cells (Bag of packed red blood cells)) based on hemoglobin of body during surgery

Category

Treatment - Drugs

2

Description

Control group 2: The second group as a control group does not receive anything

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khomeini Hospital

Full name of responsible person

Ahmad Ahmadzadeh asl

Street address

Khomeini Hospital, Shahid Ahvazian St., Ahvaz

City

Ahvaz

2

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Mozhgan Barati

Street address

Shafa Hospital, Shahid Ahvazian St., Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

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Ahvaz

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 Of Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mahin Bahadori

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work**Street address**

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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