

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the Role of Vitamin D Supplements on Pulmonary Hypertension in Patients with Thalassemia Major and Intermedia

Protocol summary

Study aim

Main Goal The Role of Vitamin D Supplements is determined on the Rate of Pulmonary Hypertension in Patients with Thalassemia Major and Intermedia.

Design

A clinical trial with control group in phase 3, parallel groups design of 14 patient for each group. Simple randomization using random sequences of integers.

Settings and conduct

In this Clinical Trial, Patients with Beta Thalassemia Major and Intermedia referred to Amir-Kabir hospital in Arak, are randomly assigned to two groups. At the onset of the Study, All Patients undergo Echocardiography to measure Pulmonary Arterial Pressure and also measure Serum Vitamin D Levels. Then a group of Patients will be treated with Vitamin D, at a dose of 500,000 units per week for 20 weeks, and the Second group will not receive any Medication. Six months later, Serum Vitamin D Levels and Pulmonary Arterial Pressure will be measured again in all Patients.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1. Parental Informed Consent 2. Patients with Thalassemia Major under Regular Transfusion and Regular Chelation. 3. Patients with Thalassemia Intermedia who do not have Regular Transfusion. Exclusion Criteria 1. Parental Dissatisfaction for Participation in the Study 2. Congenital and Non-congenital Heart Disease 3. Endocrine Disease such as Diabetes, Hypoparathyroidism and Hypothyroidism 4. Oral Intolerance

Intervention groups

Individuals in the Intervention Group are treated with Oral Vitamin D, at a dose of 500,000 units per week, for 20 weeks. Control Group's Individuals will not receive any Medication and Intervention.

Main outcome variables

Pulmonary Hypertension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190206042644N1**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **retrospective**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

Registration date

2019-03-11, 1397/12/20

Registrant information

Name

Fatemeh Fadayi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3420 4232

Email address

shaqayeqfadayi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-06-19, 1398/03/29

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-01-08, 1397/10/18

Trial completion date

empty

Scientific title

Evaluation of the Role of Vitamin D Supplements on Pulmonary Hypertension in Patients with Thalassemia Major and Intermedia

Public title

The Role of Vitamin D Supplements on Pulmonary Hypertension in Patients with Thalassemia

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Parental Informed Consent Patients with Thalassemia Major under Regular Transfusion and Regular Chelation. Patients with Thalassemia Intermedia who do not have Regular Transfusion.

Exclusion criteria:

Parental Dissatisfaction for Participation in the Study Congenital and Non-congenital Heart Disease Endocrine Disease such as Diabetes, Hypoparathyroidism and Hypothyroidism

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 28

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, using the random sequence numbers obtained from <https://www.random.org/>. In this way, each person is assigned a number from 1 to 28, then from the site, two random groups are obtained from numbers 1 to 28, the first group as the intervention group and the second group is considered as the control group.

Blinding (investigator's opinion)

Not 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 Arak University of Medical Sciences

Street address

Ethics committee of Arak University of Medical, Arak University of Medical Science, Basij Sq.

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2018-09-23, 1397/07/01

Ethics committee reference number

IR.ARAKMU.REC.1397.148

Health conditions studied**1****Description of health condition studied**

Pulmonary Hypertension

ICD-10 code

I27.0

ICD-10 code description

Primary pulmonary hypertension

2**Description of health condition studied**

Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes**1****Description**

Pulmonary Hypertension

Timepoint

Measurement of Pulmonary Arterial Pressure at the Beginning of the Study (After Entering the Study and Before the Onset of the Intervention) and Repeat Measurements 6 months after Entry into the Study.

Method of measurement

Echocardiography by Echocardiologist

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Individuals in this Group are treated with Oral Vitamin D, at a dose of 500,000 units per week, for 20 weeks.

Category

Prevention

2

Description

Control group: People in this Group will not receive any Medication and Intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-Kabir Hospital

Full name of responsible person

Fatemeh Fadayi

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Amir-Kabir Hospital, Parastar Sq., Shahid Shiroudi Ave.

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<https://arakmu.ac.ir/amirkabirhos/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjmandzadegan

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Office of the Vice-chancellor for Research, Arak University of Medical Science, Basij Sq.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Fadayi

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

make this available

Statistical Analysis Plan

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Data of Participants in this Study, which will be shared after being unidentified, include Age, Sex, Serum Levels of Vitamin D before and after intervention, and Pulmonary Arterial Pressure before and after intervention.

When the data will become available and for how long

The beginning of the Data Access Period for this Study will be One year after the Results are Published, and these Data are available for 2 years.

To whom data/document is available

This data will be accessible to researchers and students working in universities and research centers who intend to conduct supplementary studies or studies similar to this research.

Under which criteria data/document could be used

Use of data to carry out any kind of study and analysis is allowed by mentioning source.

From where data/document is obtainable

To access this data, contact one of the following ways, with "Fatemeh Fadayi" contributor: 1. Phone No.: 0098 935 0246 2. Email: Shaqayeqfadayi@gmail.com

What processes are involved for a request to access data/document

A ready-made file of shareable data will be provided, and applicants for data access, will receive the data as soon as possible after they have introduced their goal to access the data.

Comments