Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Street address
Amir-Kabir Hospital, Parastar Sq., Shahid Shiroudi Ave.
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Web page address
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
Street address
Office of the Vice-chancellor for Research, Arak University of Medical Science, Basij Sq.
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+98 86 3417 3645
Email
research@arakmu.ac.ir
Web page address
https://arakmu.ac.ir/vcr/fa
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 Stundent
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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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