

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The role of vitamin D on the left ventricle ejection fraction in thalassemia major patients with cardiac hemosiderosis in Tabriz children's hospital

Protocol summary

Study aim

Understanding the importance of treating vitamin D deficiency in patients with thalassemia major. The aim of this study is to investigate the role of vitamin D treatment in increasing left ventricular ejection fraction in hemosiderosis with the aim of improving the quality of life and survival of thalassemia major patients.

Design

Eligible children with Beta thalassemia will include in this study after obtaining consent. A code was allocated to each one of them.

Settings and conduct

Children with Beta thalassemia, that referred to Neurology Clinic of Tabriz Children Hospital will purposefully be chosen and included in the study after the diagnosis and confirmation of the TSC disease by a medical specialist and getting informed consent. The patients with underlying diseases and or with drug prohibition will be excluded from the study.

Participants/Inclusion and exclusion criteria

Children with Beta thalassemia, that referred to Neurology Clinic of Tabriz Children Hospital will purposefully be chosen and included in the study after the diagnosis and confirmation of the TSC disease by a medical specialist and getting informed consent. The patients with underlying diseases and or with drug prohibition will be excluded from the study.

Intervention groups

Based on the references, vitamin D will be administered. The patients will be evaluated for any probable side effect of the drug during the administration period.

Main outcome variables

Understanding the importance of treating vitamin D deficiency in patients with thalassemia major. The aim of this study is to investigate the role of vitamin D treatment in increasing left ventricular ejection fraction in hemosiderosis with the aim of improving the quality of life and survival of thalassemia major patients.

General information

Reason for update

Acronym

TVDTM

IRCT registration information

IRCT registration number: **IRCT20150618022805N2**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **retrospective**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

Registration date

2018-04-28, 1397/02/08

Registrant information

Name

Amir Ataollah Hiradfar

Name of organization / entity

Pediatric Health Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3526 2251

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hiradfara@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

2016-03-20, 1395/01/01

Actual recruitment end date

2017-03-21, 1396/01/01

Trial completion date

empty

Scientific title

The role of vitamin D on the left ventricle ejection fraction in thalassemia major patients with cardiac hemosiderosis in Tabriz children's hospital

Public title

The role of vitamin D on the left ventricle ejection fraction in thalassemia major patients with cardiac hemosiderosis in Tabriz children's hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Reduction of left ventricular ejection fraction by less than 55% based on echocardiography of the last three months
3. Treated with heart failure diagnosis by heart service
4. Level 25-Hydroxyvitamin D less than 30 ng / dl
5. Normal PTH serum levels
6. Serum magnesium levels are normal

Exclusion criteria:

1. Exacerbation of heart failure
2. Occurrence of arrhythmias
3. Serum 25-Hydroxyvitamin D levels greater than 80 ng / dl
4. Severe constipation
5. Muscle weakness

Age

From **6 months** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **125**

Actual sample size reached: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients referred to the study are randomly divided into control and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional Ethics Committee, Office of the Vice

Chancellor for Research, Tabriz University of Medical

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz, PO Box: 5165665931, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2018-03-18, 1396/12/27

Ethics committee reference number

IR.TBZMED.REC.1396.1287

Health conditions studied

1

Description of health condition studied

Major thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassemia

Primary outcomes

1

Description

Vitamin D

Timepoint

Every 4 weeks

Method of measurement

Blood sample-questionnaire

2

Description

Heart hemosiderosis

Timepoint

Every 4 weeks

Method of measurement

Echocardiography-questionnaire

Secondary outcomes

1

Description

Constipation

Timepoint

During the administration period

Method of measurement

En Clinical Examination, Questionnaire

Intervention groups

1

Description

Vitamin D will be administered intramuscularly at a dosage of 50,000 units for the case group for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Dr amir ataloah hiradfar

Street address

Tabriz Children Hospital, Sheshgelan Street, Tabriz, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Barzegar

Street address

Pediatric Health Research Center, Tabriz Children Hospital, Sheshgelan Street, Tabriz, Iran.

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. amir ataloah hiradfar

Position

Pediatric Oncologist, Professor, Faculty Member

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Pediatric Health Research Center, Children Hospital, Sheshgelan street, Tabriz, Iran.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
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Dr Aziz Hasanzadeh
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Understanding the importance of treating vitamin D deficiency in patients with thalassemia major The aim of this study is to investigate the role of vitamin D treatment in increasing left ventricular ejection fraction in hemosidosis with the aim of improving the quality of life and survival of thalassemia major patients.

When the data will become available and for how long

n/a

To whom data/document is available

n/a

Under which criteria data/document could be used

n/a

From where data/document is obtainable

n/a

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

n/a

Comments