

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of vit D supplement on ejection fraction, ferritin and hypertention in beta-thalassaemia major patients

Protocol summary

Summary

The aim of this study was the effect of vitamin D supplementation on cardiac output, pulmonary artery pressure, serum ferritin and blood pressure in patients with thalassemia major is. This study is a clinical trial 33 patients with thalassemia referred to thalassemia ward has Exclusion criteria: other concurrent diseases, including heart disease; Diabetes; Hepatitis; Hypo-parathyroid; Less than 35% of cardiac output method selected by convenience sampling thalassemia major, iron overload is that they have no heart or sediment are mild, measured levels of vitamin D, ferritin and blood pressure measurement is performed. In case of low vit D of 74 nmol l or 29 ng per ml, is studied. The patients underwent echocardiography and cardiac output are measured and also vitamin D3 during the twelve week treatment at a dose of 50,000 IU per week begins. After 3 months, the level of vitamin D, ferritin and blood pressure were measured and in case of normal vitamin D levels, the second echo is done. Low vitamin D in vitamin D treatment will be repeated once again. Patients with improved cardiac output, blood pressure, pulmonary blood pressure ferritin levels are considered to be responding to treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022110222N5**

Registration date: **2016-03-04, 1394/12/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-04, 1394/12/14

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

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Email address

keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vit D supplement on ejection fraction, ferritin and hypertention in beta-thalassaemia major patients

Public title

The effect of vit D supplement on ejection fraction, ferritin and hypertention in beta-thalassaemia major patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients with thalassemia major with vitamin D levels less than 74 nmol . L or 29 ng . ml

Exclusion criteria: other concurrent diseases, including heart disease; Diabetes; Hepatitis; Hypo-parathyroid; Cardiac output less than 35%

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 33

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

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Shahrekord, Shahrekord University of Medical Sciences

City

Shahrekord

Postal code

Approval date

2015-08-30, 1394/06/08

Ethics committee reference number

IR.SKUMS.REC.1394.63

Health conditions studied

1

Description of health condition studied

cooley anemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

cardiac out put

Timepoint

Baseline and Three months later

Method of measurement

echocardiography

2

Description

blood pressure

Timepoint

Baseline and Three months later

Method of measurement

Barometer

3

Description

pulmonary hypertension

Timepoint

Baseline and quarterly

Method of measurement

echocardiography

4

Description

ferritin level

Timepoint

Baseline and Three months later

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Patients with thalassemia major with iron overload or precipitate heart they do have mild, measured levels of vitamin D, ferritin and blood pressure measurement is performed. Vit D level of 74 nmol being in lower case I or 29 ng per mm Lytrbashnd, is studied. The patients underwent echocardiography and cardiac output are measured and also vitamin D3 during the twelve week treatment at a dose of 50,000 IU per week begins. After 3 months, the level of vitamin D, ferritin and blood pressure were measured and in case of normal vitamin D levels, the second echo is done. Low vitamin D in vitamin D treatment will be repeated once again

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Kiavash Fekri

Street address

Shahrekord, Shahrekord University Of Medical Sciences

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahrekord University of Medical Science

Full name of responsible person

Dr.Kamal Solati

Street address

Shahrekord, Shahrekord University of Medical Sciences

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Shahrekord

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 Shahrekord University of Medical Science

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

Shahrekord University of Medical Sciences

Full name of responsible person

Kiavash Fekri

Position

Professor of Pediatrics, Assistant Professor

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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