

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Vitamin D levels in children with chronic idiopathic thrombocytopenic purpura and the effect of vitamin D supplementation on platelet increase

Protocol summary

Study aim

Determining vitamin D levels in children with chronic idiopathic thrombocytopenic purpura and the effect of vitamin D supplementation on platelet increase

Design

Clinical trial study, without control group, without blinding, non-randomized- underwent on 35 patients

Settings and conduct

The technique of data collection is a census. After obtaining permission with keeping the patients' information confidential, all patients with the above characteristics at Afzalipur Hospital will be evaluated for vitamin D deficiency and the effect of vitamin D supplementation. If their serum vitamin D level was less than 30 mg/dL, they will be given vitamin D according to the table above, and their vitamin D and platelet levels will be checked three and nine months later.

Participants/Inclusion and exclusion criteria

The criteria for entry into the study included having vitamin D level lower than 30 mg/dl, a diagnosis of chronic ITP and giving informed consent. The criteria for exiting into the study included having incomplete demographic data, being reluctant to participate in the study, a history of taking vitamin D supplements for the previous 3 months at a therapeutic dose, a change in the dosage of the medications taken, and a Severe and dangerous drop in platelet levels and need for hospitalization.

Intervention groups

In patients with vitamin D levels below 30 mg/dl, vitamin D supplementation will be administered at 400 units per day for children under 1 year of age and 600 units per day for children 1-18 years of age.

Main outcome variables

Platelet counts prior to and following supplementation with vitamin D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220817055737N1**

Registration date: **2022-12-23, 1401/10/02**

Registration timing: **retrospective**

Last update: **2022-12-23, 1401/10/02**

Update count: **0**

Registration date

2022-12-23, 1401/10/02

Registrant information

Name

Abolfazl Gilani

Name of organization / entity

Tehran University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

a-gilani@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-04-23, 1401/02/03

Actual recruitment start date

2022-02-19, 1400/11/30

Actual recruitment end date

2022-07-21, 1401/04/30

Trial completion date

2022-07-21, 1401/04/30

Scientific title

Vitamin D levels in children with chronic idiopathic thrombocytopenic purpura and the effect of vitamin D supplementation on platelet increase

Public title

Effect of vitamin D on platelet increase in chronic idiopathic thrombocytopenic purpura

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of chronic ITP Giving informed consent vitamin D level lower than 30 mg/dl

Exclusion criteria:

Incomplete demographic data Being reluctant to participate in the study History of taking vitamin D supplements for the previous 3 months at a therapeutic dose Change in the dosage of the medications taken Severe and dangerous drop in platelet levels and need for hospitalization

Age

To **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **35**

Actual sample size reached: **35**

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 Afzalipour hospital-Kerman
University of Medical Sciences

Street address

Afzalipour hospital- Imam highway- Kerman

City

Kerman

Province

Kerman

Postal code

13911-76169

Approval date

2022-02-01, 1400/11/12

Ethics committee reference number

IR.KMU.AH.REC.1400.285

Health conditions studied

1

Description of health condition studied

Chronic Idiopathic Thrombocytopenic Purpura

ICD-10 code

D69.3

ICD-10 code description

Immune thrombocytopenic purpura

Primary outcomes

1

Description

Platelet counts prior to and following supplementation with vitamin D

Timepoint

Blood platelet levels were measured at the beginning of the trial and 3 & 9 months following the initiation of vitamin D supplementation.

Method of measurement

Blood platelet levels

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In patients with vitamin D levels below 30 mg/dl, vitamin D supplementation will be administered at 400 units per day for children under 1 year of age and 600 units per day for children 1-18 years of age.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Blood clinic- Afzalipour hospital

Full name of responsible person

Noushin Jahantighi

Street address

Afzalipour hospital, Imam Highway, Kerman

City

Kerman
Province
Kerman
Postal code
13911-76169
Phone
+98 34 3132 8000
Email
international@kmu.ac.ir

2

Recruitment center

Name of recruitment center
Endocrine clinic-Afzalipour hospital
Full name of responsible person
Farzaneh Yazdi
Street address
Afzalipour hospital, Imam Highway,Kerman
City
Kerman
Province
Kerman
Postal code
13911-76169
Phone
+98 34 3322 2250
Email
drfarzaneh.yazdi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Reza Malekpour Afshar
Street address
Kerman University of medical sciences Vice
Chancellor-Ebn -Sina St-Tahmasb Abad-Kerman
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3857
Email
vcr@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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
Roham Sarmadian
Position
Research Asistant
Latest degree
Medical doctor
Other areas of specialty/work
Infectious diseases
Street address
infectious Disease Research Center,Arak University of
Mediact Sciences,Arak
City
Arak
Province
Markazi
Postal code
3813691954
Phone
+98 86 3147 3521
Email
rsarmadian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Pouria Salajegheh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Afzalipour Hospital- Imam highway- Kerman
City
کرمان
Province
Kerman
Postal code
13911-76169
Phone
+98 34 3245 8892
Email
salajegheh.poorya@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abolfazl Gilani

Position

Research Assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Tehran University of Medical Sciences, Poursina
St, Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8889 6696

Fax**Email**

Abol.gilani95@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After de-identification, data on research outcomes are available for release.

When the data will become available and for how long

Access to the data is permitted for up to 2 years following the completion of the study and publication of the study and publication of the study's main article.

To whom data/document is available

The data and the outcomes of which will be published in the form of article will only be accessible to the researchers from academic institutions collaborating with Kerman University of Medical Sciences.

Under which criteria data/document could be used

The suggested study protocol must be submitted to Kerman University of Medical Sciences, and the university's scientific-technical committee must approve its scientific validity and relevance.

From where data/document is obtainable

Mr. Poorya Salajegheh can be contacted at the email address salajegheh.poorya@gmail.com.

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

The relevant requests will be provided to the requesting researcher as a collaborative project following assessment and approval by the relevant officials.

Comments