

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of different levels of vitamin D on the supply of children with inflammatory bowel disease

Protocol summary

Summary

The purpose of this project is to determine the effect of administering different amounts of vitamin D to the needs of children with inflammatory bowel disease to this vitamin, which is done randomly, double blind and multi-center, including all government centers that have clients with this disease. This study was performed in Phase III clinical trials on 30 patients in each group, including patients receiving 800 units of vitamin D per day and other group that receiving 3,000 units of vitamin per day in 6 weeks. The main inclusion criteria are baby's infant's bowel inflammatory bowel disease include Crohn's disease or colitis and patient satisfaction. The main exclusion criterion is the lack of proper testing of the patient, as well as the patient's dissatisfaction with the continuation or death of the patient. Initially, the symptoms and severity of the disease were measured by a questionnaire. During and after the treatment, the amount of vitamin D, serum albumin, calcium and phosphate ions was measured in each exact test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011075123N1**
Registration date: **2017-07-15, 1396/04/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-15, 1396/04/24

Registrant information

Name

Hamidreza Kianifar

Name of organization / entity

Mashahd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of different levels of vitamin D on the supply of children with inflammatory bowel disease

Public title

The effect of vitamin D on the improvement of abdominal pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Inflammatory bowel disease; patient and patient's parents satisfaction Exclusion criteria: Failure to perform tests in all project stages; taking the supplementation incorrectly; patient dissatisfaction for continuation of the project

Age

From **1 year** old to **24 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Daneshgah Street Qureshi building

City

Mashhad

Postal code

Approval date

2016-11-09, 1395/08/19

Ethics committee reference number

IR.MUMS.fm.REC.1395.232

Health conditions studied

1

Description of health condition studied

Inflammatory Bowel Disease

ICD-10 code

(K50-K52)

ICD-10 code description

Noninfective inflammatory bowel disease

Primary outcomes

1

Description

Clinical Symptoms

Timepoint

Before the trial

Method of measurement

Questionnaire

2

Description

Severity of disease

Timepoint

Before the trial

Method of measurement

Questionnaire

Secondary outcomes

1

Description

VIT D

Timepoint

After the trial

Method of measurement

HPLC

2

Description

Ca & P

Timepoint

After the trial

Method of measurement

Enzymatic

3

Description

Level of serumic Albmin

Timepoint

After the trial

Method of measurement

Enzymatic

4

Description

Level of serumic Ferritin

Timepoint

After the trial

Method of measurement

chemoluminescence

Intervention groups

1

Description

In the first intervention group, daily dose of 800 units of vitamin D is administered for 6 weeks. because the availability of 50,000 single pearls on the market, aggregate daily doses may be given as one pearl every few weeks.

Category

Treatment - Drugs

2

Description

In the second intervention group, daily dose of 3000 units of vitamin D is administered for 6 weeks. because the availability of 50,000 single pearls on the market, aggregate daily doses may be given as one pearl every few weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem Hospital

Full name of responsible person**Street address****City**

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Daneshgah Ave,Ghoreishi, Mashhad

City

Mshhad

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, Mashhad University of Medical Sciences

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**

Mashhad University of Medical Sciences

Full name of responsible person

Majid Khademian

Position

Fellows in Training

Other areas of specialty/work**Street address**

Department of Pediatrics, Hospital Ghaem, Ahmadabad streets, Mashhad

City

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Hamidreza Kianifar

Position

Full Professor

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Majid Khademian

Position**Other areas of specialty/work****Street address****City**

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Postal code**Phone**

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Fax**Email****Web page address****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