

# 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

+98 51 1801 2469

###### Email address

kianifarhr@mums.ac.ir

###### 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 Feritin

#### 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**

Mashhad

**Postal code****Phone**

+98 51 3801 2753

**Fax****Email**

khademianm941@mums.ac.ir

**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

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

Department of Peditrics,Ghaem Hospital , Ahmadabad streets, Mashhad

**City**

Mashhad

**Postal code****Phone**

+98 51 3801 2753

**Fax****Email**

KianifarHR@mums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Majid Khademian

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

Mashhad

**Postal code****Phone**

00

**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*