

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Association between Vitamin D deficiency in patients with inflammatory bowel disease and disease activity, TNF alpha level and quality of life

Protocol summary

Summary

This study has been designed in order to decrease of serum level of TNF-alpha and disease activity index of IBD patients referring to Taleghani Hospital, Tehran, Iran. This study is a randomized, double-blind, study with control group. The study populations consist of 120 IBD patients referred to Taleghani hospital. IBD patients are diagnosed based upon clinical, endoscopic, radiological and histological criteria findings by an experienced gastroenterologist. Their serum level of 25(OH) vitD3 should be <30ng/ml. Patients with Positive anti TTG test lab, history of hypercalcemia, kidney disorders requiring dialysis and pregnant women are excluded from this study. These patients are divided into treatment and control groups in randomized, double blind. Initial level of serum 25(OH) 2D3 and level of serum TNF alpha are measured. Treatment group will take 50000 iu vitamin D, one time a week for 12 weeks. After 12 weeks serum level of 25(OH) 2D3 and serum level of TNF alpha is be measured in two groups again. The difference between first and second level TNF alpha and 25(OH) 2D3 in two groups is compared by statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122915686N1**

Registration date: **2013-12-29, 1392/10/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-29, 1392/10/08

Registrant information

Name

Mohammad Hosein Safapoor

Name of organization / entity

Research center of gastroenterology and liver disease

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2515

Email address

mh.safapoor@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center of gastroenterology and liver disease

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Association between Vitamin D deficiency in patients with inflammatory bowel disease and disease activity, TNF alpha level and quality of life

Public title

Effect of vitamin D in the treatment of inflammatory bowel disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: IBD patients are diagnosed based upon clinical, endoscopic, radiological and histological criteria findings by an experienced gastroenterologist.

Exclusion criteria: serum level of 25(OH)vitD3>30ng/ml; positive anti TTG test lab; history of hypercalcemia;

kidney disorders requiring dialysis and pregnancy.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

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**

Research center of gastroenterology and liver disease

Street address

7th floor, Taleghani Hospital, velenjak, Tehran

City

Tehran

Postal code**Approval date**

2013-03-15, 1391/12/25

Ethics committee reference number

669

Health conditions studied**1****Description of health condition studied**

inflammatory bowel disease

ICD-10 code

k50, k51

ICD-10 code description

Crohn disease of small intestine,Ulcerative colitis

Primary outcomes**1****Description**

25(OH)D3 level

Timepoint

Three months after the intervention

Method of measurement

ELISA Method (ng/ ml)

2**Description**

TNF alpha level

Timepoint

Three months after the intervention

Method of measurement

ELISA Method (ng/ ml)

3**Description**

Activity Index

Timepoint

Three months after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group receive vitamin D pearl with 50000 unit once a week up to 12 weeks.

Category

Treatment - Drugs

2**Description**

The control group did not receive any medication.

Category

N/A

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

Taleghani Hospital, Gastroenterology ward

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

Tehran

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

Research center of gastroenterology and liver disease of Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Zali

Street address

7th floor, Taleghani Hospital, Velenjak, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research center of gastroenterology and liver disease of Beheshti 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

Taleghani Hospital

Full name of responsible person

Dr. Mohammad Hosein Safapoor

Position

Gastroenterologist

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research center of Gastroenterology and liver

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Full name of responsible person

Dr. Hamid Asad zadeh

Position

Gastroenterologist

Other areas of specialty/work

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hamid.assadzadeh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Research center of gastroenterology and liver disease

Full name of responsible person

Tahereh Dadaei

Position

Researcher

Other areas of specialty/work

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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