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 gasteroenterology 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 gasteroenterology 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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Person responsible for scientific inquiries

Contact

Name of organization / entity
Recearch center of Gasteroenterology and liver disease

Full name of responsible person
Dr. Hamid Asad zadeh

Position
Gastroenterologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Recearch center of gasteroenterology and liver disease

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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