Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of The Effects of vitamin D3 supplementation on Irritable bowel syndrome symptoms

Protocol summary

Summary

In this study , 66 patients with irritable bowel syndrome, attending counseling and treatment center for gastrointestinal diseases, with the inclusion criteria randomly assig to two groups. The first group take one vitamin D3 (50000 IU) weekly for 2 months, in addition to dietary recommendations. The second group , along with dietary recommendations take placebo. Serum level of 25(OH)D and clinical signs of disease (abdominal pain, bloating , diarrhea and constipation) , and quality of life (questionnaire) are measured before the treatment and after its completion. The effect of vitamin D3 supplementation is compared to placebo in order to investigate the effect of vitamin D3 in improving the symptoms of irritable bowel syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402234010N11**
Registration date: **2014-04-04, 1393/01/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-04, 1393/01/15

Registrant information

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Azita Hekmatdoost
Name of organization / entity
Shahid Beheshti University of Medical Sciences, National Institute of Nutrition Research
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Recruitment status

Recruitment complete

Funding source

There is no funding support for this study.

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-07-11, 1392/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of The Effects of vitamin D3 supplementation on Irritable bowel syndrome symptoms

Public title

Evaluation of the Effects of vitamin D3 supplementation on Irritable bowel syndrome symptoms.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 65 years old; serum level of 25(OH)D under 30 ng/ml; evidence of having irritable bowel syndrome using Rome III Criteria; not having Vitamin D supplementation since one year ago; not having a history of alcohol drink; not suffering from other organic diseases of the intestine, bowel surgery, breast; cancer, severe mental illness; not pregnant, breastfeeding and professional sports; not taking Non-steroidal anti-inflammatory drug (NSAIDs), laxatives, nicotine, artificial sweeteners, antibiotics, immunomodulators or repression, intestinal bleeding, drugs, fish oils and digestive movements modifier.

Exclusion criteria: their unwillingness to continue the study for any reason; pregnancy.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
National Nutrition and Food Technology Research Institute (NNFTRI)

Street address
#7, Shahrak Gharb, Shahid Farahzadi Blvd, Shahid Hafezi St., No. 7.

City
Tehran

Postal code
1981619573

Approval date
2012-12-07, 1391/09/17

Ethics committee reference number
116/3976

Health conditions studied

1

Description of health condition studied
Irritable Bowel Syndrome

ICD-10 code
k58

ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
25 (OH) D

Timepoint
before and after studu (end of second month)

Method of measurement
ELISA

2

Description
constipation

Timepoint
before and after study (end of second month)

Method of measurement
question

3

Description
Diarrhea

Timepoint
before and after study (end of second month)

Method of measurement
question

4

Description
Bloating and abdominal pain

Timepoint
before and after study (end of second month)

Method of measurement
question

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1: In intervention group: - oral vitamin D3 (50000IU), one per week, for 2 months. classifying Intervention: drug intervention using drug.

Category
Treatment - Drugs

2

Description
Intervention 2: In placebo group: capsules containing rice flour (placebo), one per week for 2 months. - classifying intervention: intervention with placebo.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastrointestinal Clinic

Full name of responsible person
Dr Azita Hekmatdoost

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Nutrition and Food Technology Research Institute (NNFTRI)

Full name of responsible person
Dr. Majid Haji Faraji

Street address
#7, Shahrak Gharb, Farahzadi Blvd, Hafezieh St (Arghavan Gharbi), No 7.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
National Nutrition and Food Technology Research Institute (NNFTRI)

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
National Nutrition and Food Technology Research Institute (NNFTRI)

Full name of responsible person
Dr. Azita Hekmatdoost

Position
Associate Prof

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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