

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effects of supplementation with vitamin D on clinical outcomes, quality of life, anxiety, serum CRH and IL-6 in Patient with irritable bowel syndrome the predominant form diarrhea

Protocol summary

Summary

The main purpose: to determine the effect of vitamin D on clinical outcomes, quality of life, stress and anxiety, serum concentrations of CRH and IL-6 in patients with irritable bowel syndrome with predominant form of diarrhea; Study design: Randomized, double-blind, placebo-controlled, single-center, phase II trial; Randomization Details: For randomization, the permuted block randomization will be used with quadruple blocks. According to the sample size of 88, which is set, 22 blocks will be produced using www.sealedenvelope.com. In order to apply the concealment in the randomization process, unique codes will be used on complementary boxes, the code being generated by the software. study population: patients with irritable bowel syndrome with diarrhea admitted to hospital the Prophet (PBUH) Inclusion criteria: age between 18 to 65 years, diagnosed with irritable bowel syndrome with diarrhea forms and questionnaires completed by ROME III criteria for the diagnosis of IBS, their disease severity score is between 175 to 300, BMI is between 18.5 and 34.9, don't have abdominal illness and abdominal surgery, they don't use vitamin D in the last 6 months. Probiotic supplements and do not use antidepressants. Exclusion criteria from the study: the creation of any abnormal response to supplements, gastrointestinal bleeding, blood in the stool, loss weight fast, levels of vitamin D normal (above 30 nmol / L), taking less than 80 percent complete and wanting person to continue to cooperate. Intervention: Supplementation with vitamin D or a placebo intervention period: 3 months sample size:44 person in each group The primary outcome: improvement of clinical symptoms, disease severity, quality of life and stress and anxiety Secondary outcomes: serum levels of Corticotropin Releasing Hormone and Inter Lukin-6

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709232709N45**

Registration date: **2017-10-04, 1396/07/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-04, 1396/07/12

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Colorectal Research Center of Rasool Akram Hospital

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of supplementation with vitamin D on clinical outcomes, quality of life, anxiety, serum CRH and IL-6 in Patient with irritable bowel syndrome the predominant form diarrhea

Public title

The effect of vitamin D supplementation on patients with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for the study: aged between 18 and 65 years; suffering from irritable bowel syndrome ROME III criteria and completed the questionnaires; their disease severity score is between 175 and 300; BMI Between 18.5 to 34.9; a resident of Tehran; have diarrhea-predominant irritable bowel syndrome with form. Non-inclusion criteria: pregnant women or nursing mothers; a history of gastrointestinal diseases, including IBD, colorectal cancer and...; Gastrointestinal diseases such as celiac disease, is an infection of the gastrointestinal tract and ...; Abdominal surgery or radiation therapy, cholecystectomy, etc. The use of vitamin D supplements, six months before; Use of now any type of supplement or 3 months; probiotic supplement use; Antidepressants uses (Including serotonin receptor antagonists, tricyclic antidepressants, selective serotonin reuptake inhibitors, etc.); High-dose alcohol and caffeine 24 hours before the test; smoking 48 hours before the test; Exclusion criteria: Create any abnormal reactions to supplements; gastrointestinal bleeding; blood in the stool; rapid weight loss; the level of vitamin D normal (above 30 nmol / L); less than 80 percent of supplements; no intention to continue cooperation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences.

Street address

Iran University of Medical Sciences, next to the Tower and Milad Hospital, Hemmat Highway

City

Tehran

Postal code

Approval date

2017-06-19, 1396/03/29

Ethics committee reference number

IR.IUMS.REC 1396.30232

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrome

ICD-10 code

K58.0

ICD-10 code description

Irritable bowel syndrome with diarrhoea

Primary outcomes

1

Description

Clinical signs

Timepoint

Before and after 3 months of intervention

Method of measurement

ROME IV questionnaire and World Gastroenterology Organization questionnaire for the diagnosis of irritable bowel syndrome

2

Description

Severity of Clinical symptoms

Timepoint

Before and after 3 months of intervention

Method of measurement

IBS symptom severity questionnaire.

3

Description

Quality of life

Timepoint

Before and after 3 months of intervention

Method of measurement

Irritable Bowel Syndrome Quality of Life Questionnaire.

Secondary outcomes

1

Description

Anxiety

Timepoint

Before and after 3 months of intervention

Method of measurement

Hospital Anxiety and Depression Scale(HADS)

2

Description

Corticotropin Releasing Hormone

Timepoint

Before and after 3 months of intervention

Method of measurement

Elisea

3

Description

Interlukin-6

Timepoint

Before and after 3 months of intervention

Method of measurement

Elisea

Intervention groups

1

Description

Receiving vitamin D from Zahrawi Company with 50,000 international units weekly in intervention group

Category

Treatment - Drugs

2

Description

Filled with edible paraffin placebo produced by Zahrawi Co. was performed weekly in the control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational Research Center Rasoule Akram Hospital

Full name of responsible person

Marjan Mokhtare

Street address

Educational Research Center Rasoule Akram Hospital,
Niayesh street, Shahrara street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research,Iran University of
Medical Sciences

Full name of responsible person

Doctor Iraj Alimohammadi

Street address

Iran University of Medical Sciences, next to the Tower
and Milad Hospital, Hemmat Highway

City

Tehran

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,Iran 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

Iran University Medical Sciences

Full name of responsible person

Masoumeh Khalighi Sikaroudi

Position

Student Masters

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Iran University Medical of Sciences

Full name of responsible person

Masoumeh Khalighi Sikaroudi

Position

Student Masters