Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of supplementation with vitamin D on clinical outcomes, quality of life, anxiety, serum serotonin (5-hydroxytryptamine), 5-hydroxy-indole acetic acid and ratio of 5-HIAA/ 5-HT 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 serotonin (5-hydroxytryptamine), 5-hydroxy-indole acetic acid and the 5 HIAA to 5 HT in patients with irritable bowel syndrome with predominant form of diarrhea Study design: Randomized, double-blind, placebo-controlled, single-center, phase II trial study population: patients with irritable bowel syndrome with diarrhea admitted to hospital the Prophet (PBUH) Inclusion criteria: age between 18 to 60 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 serotonin and 5-hydroxy-indole acetic acid

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701162709N42**

Registration date: **2017-06-02, 1396/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-02, 1396/03/12

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

private sector

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-05-05, 1396/02/15

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 serotonin (5-hydroxytryptamine), 5-hydroxy-indole acetic acid and ratio of 5-HIAA/ 5-HT 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
Other

Inclusion/Exclusion criteria
Inclusion criteria for the study: aged between 18 and 60 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. (If your gallbladder is removed, the probability malabsorption of fat and vitamin D absorption.); 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
N/A

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
Iran University of Medical Sciences and Health Services Ethics Committee

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

City
Tehran

Postal code

Approval date
2017-01-02, 1395/10/13

Ethics committee reference number
IR.IUMS.REC 1395.9413323001

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
Quality of life

Timepoint
Before and after 3 months of intervention

Method of measurement
Irritable Bowel Syndrome Quality of Life Questionnaire.

2

Description
Severity of Clinical symptoms

Timepoint
Before and after 3 months of intervention

Method of measurement
IBS symptom severity questionnaire.

3

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

Secondary outcomes

1

Description
Anxiety
Timepoint
Before and after 3 months of intervention
Method of measurement
Hospital Anxiety and Depression Scale(HADS)

2

Description
Serum levels of serotonin
Timepoint
Before and after 3 months of intervention
Method of measurement
Blood serum in terms of nmol /L

3

Description
Serum levels of 5-hydroxy indole acetic acid
Timepoint
Before and after 3 months of intervention
Method of measurement
Blood serum in terms of nmol /L

Intervention groups

1

Description
Vitamin D in the intervention group
Category
Treatment - Drugs

2

Description
Filled with edible paraffin placebo in control group
Category
Treatment - Drugs

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
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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