

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of vitamin D3 supplementation on clinical signs, inflammatory and oxidative stress bio-markers in patients with Irritable Bowel Syndrome: A randomized double blinded clinical trial

Protocol summary

Summary

The purpose of this study is to evaluate the effect of vitamin D supplementation on markers of inflammation and oxidative stress and clinical signs in patients with Irritable Bowel Syndrome (IBS). This randomized double blind clinical trial will be performed on 90 patients (45 in intervention and 45 in control group) with IBS. The intervention group will receive 50000 IU vitamin D3 and the control group will receive placebo contains edible paraffin once every two weeks for six months. Variables including markers of inflammation and oxidative stress, serum levels of calcium and vitamin D3, anthropometric indicators and blood pressure will be measured at baseline and end of the study. We will use Rome III questionnaire for evaluating the clinical signs of the disease. The questionnaires will be filled out at baseline and every two weeks by the patients for six months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042521935N1**

Registration date: **2015-10-27, 1394/08/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-27, 1394/08/05

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences and Health Services

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-05-26, 1394/03/05

Expected recruitment end date

2015-11-25, 1394/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of vitamin D3 supplementation on clinical signs, inflammatory and oxidative stress bio-markers in patients with Irritable Bowel Syndrome: A randomized double blinded clinical trial

Public title

The effect of vitamin D3 supplementation in treatment of Irritable Bowel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Including criteria: the patients who are 19-60 years old diagnosed with Irritable Bowel Syndrome (IBS) according to ROME III criteria; Signed consent by the patient.

Exclusion criteria: The patients who have celiac disease (diagnosed by a duodenal biopsy or celiac serological

tests), any other diseases of the gastrointestinal tract such as IBD, any kind of abdominal surgery, chronic disease such as diabetes, cardiovascular, hepatic, kidney and severe infection; Pregnancy; Breastfeeding; Smoking; Alcohol consumption; Use of dietary supplements; Use of vitamin D and calcium supplement during the last year before the study; Use any medication for improvement of disease signs during the study period.

Age

From **19 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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 Ahvaz Jundishapur University Of Medical Sciences

Street address

Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd. Ahvaz

City

Ahvaz

Postal code**Approval date**

2015-05-25, 1394/03/04

Ethics committee reference number

ir.ajums.rec.1394.306

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

Irritable bowel syndrome

ICD-10 code

k58

ICD-10 code description

Irritable colon

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

TNF- α

Timepoint

Before and after of six months intervention

Method of measurement

ELISA

2**Description**

IL-10

Timepoint

Before and after of six months intervention

Method of measurement

ELISA

3**Description**

IL-17

Timepoint

Before and after of six months intervention

Method of measurement

ELISA

4**Description**

Malondialdehyde (MDA)

Timepoint

Before and after of six months intervention

Method of measurement

Thiobarbituric Acid assay

5**Description**

Total antioxidant capacity (TAC)

Timepoint

Before and after of six months intervention

Method of measurement

Colorimetric method

6**Description**

Serum vitamin D

Timepoint

Before and after of six months intervention

Method of measurement

Radioimmunoassay

7**Description**

Clinical symptoms (discomfort in the abdomen, abdominal pain, bloating, and disapproval of stool consistency)

Timepoint

Baseline and every two weeks for six months

Method of measurement

Rome III questionnaire

8

Description

Calcium

Timepoint

Before and after of six months intervention

Method of measurement

Arsenaco III method

Secondary outcomes

1

Description

Weight

Timepoint

Before and after of six months intervention

Method of measurement

Digital scale

2

Description

Body Mass Index (BMI)

Timepoint

Before and after of six months intervention

Method of measurement

Weight to height squared ratio

3

Description

Waist circumference

Timepoint

Before and after of six months intervention

Method of measurement

Tape measure

4

Description

Hip circumference

Timepoint

Before and after of six months intervention

Method of measurement

Tape measure

5

Description

Physical Activity (PA)

Timepoint

Before and after of six months intervention

Method of measurement

Physical activity questionnaire

6

Description

Dietary intake

Timepoint

Before and after of three and six months intervention

Method of measurement

24-hour food recall questionnaire

7

Description

Blood pressure

Timepoint

Before and after of six months intervention

Method of measurement

Blood pressure monitor

Intervention groups

1

Description

Intervention group: Cholecalciferol (vitamin D3) 50000 IU, once every two weeks, for six months

Category

Treatment - Drugs

2

Description

Control group: Edible paraffin as placebo, once every two weeks, for six months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Street address

Ahvaz Imam Khomeini Hospital, Azadegan St, Ahvaz.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saaki

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd. Ahvaz

City
Ahvaz

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, Ahvaz Jundishapur 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
Ahvaz Jundishapur University Of Medical Sciences

Full name of responsible person
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Position
Ph.D candidate of nutrition

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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