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

Amir Abbasnezhad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 443440992

Email address

abbasnezhad91@gmail.com

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
Amir Abbasnezhad
Position
Ph.D candidate of nutrition
Other areas of specialty/work
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd. Ahvaz
City
Ahvaz
Postal code
Phone
+98 61 3373 8319
Fax
Email
abbasnezhad91@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Judishapur University of Medical Sciences
Full name of responsible person
Reza Amani
Position
Associate Professor of nutrition group
Other areas of specialty/work
Street address
Ahvaz Judishapur University of Medical Sciences, Golestan Blvd. Ahvaz
City
Ahvaz
Postal code
Phone
+98 61 3373 8319
Fax
Email
rezaamani@hotmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Siences
Full name of responsible person
Amir Abbasnezhad
Position
Ph.D candidate of nutrition
Other areas of specialty/work
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd. Ahvaz
City
Ahvaz
Postal code
Phone
+98 61 3373 8319
Fax
Email
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