Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Vitamin D3 on Quality of Life and Symptoms of patients with Irritable Bowel Syndrome and vitamin D3 Deficiency

Protocol summary

Study aim

The Effect of Vitamin D3 on Quality of Life and Symptoms of patients with Irritable Bowel Syndrome and vitamin D3 Deficiency

Design

In this study, 50 patients with irritable bowel syndrome participated. These patients receive 300,000 units of vitamin D intramuscularly. The clinical trial phase of this study is 2-3. In this study, the questionnaire of irritable bowel symptoms and quality of life of patients is completed and measured before the intervention and 4 weeks after the injection of vitamin D.This study has no control group.

Settings and conduct

The study site is Arak University of Medical Sciences. First, the symptoms of irritable bowel syndrome, patients' quality of life, and their vitamin D levels are measured. They enter the study if they have the conditions to study. These patients receive 300,000 units of vitamin D intramuscularly. At the end of the 4-week intervention phase, the rate of irritable bowel symptoms and quality of life of patients are measured and the effectiveness of vitamin D is compared with before the intervention.

Participants/Inclusion and exclusion criteria

Patients with irritable bowel syndrome with vitamin D levels between 15 and 30 ng / ml are included in the study. These patients should not have had bowel surgery. If a participant becomes allergic to vitamin D during the study or is unable to continue the study, he or she will be excluded.

Intervention groups

Intervention group: Vitamin D3 (calciferol) in the amount of 300,000 units is administered intramuscularly for this group.

Main outcome variables

Gastrointestinal symptoms and irritable bowel syndrome; Quality of life of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180617040114N4**
Registration date: **2020-12-16, 1399/09/26**
Registration timing: **retrospective**

Last update: **2020-12-16, 1399/09/26**
Update count: **0**

Registration date

2020-12-16, 1399/09/26

Registrant information

Name

jamal Amri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-26, 1399/02/07

Expected recruitment end date

2020-12-09, 1399/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Vitamin D3 on Quality of Life and Symptoms of patients with Irritable Bowel Syndrome and vitamin D3 Deficiency

Public title
The effect of vitamin D3 on the symptoms of patients with irritable bowel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Vitamin D levels between 15-30 ng/ml Absence of any gastrointestinal surgery Lack of severe mental and behavioral disorders Patients with irritable bowel syndrome according to the diagnosis of a gastroenterologist according to ROME-III criteria
Exclusion criteria:
Consumption a vitamin D supplement one year before enrollment. Consumption of nicotine and its derivatives in the last 6 months
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Aral University of Medical Sciences,Basij Square
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2020-04-25, 1399/02/06
Ethics committee reference number
IR.ARAKMU.REC.1399.027

Health conditions studied

1

Description of health condition studied
Patients with irritable bowel syndrome
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Degree of gastrointestinal symptoms and irritable bowel syndrome
Timepoint
It is measured one day before the intervention and 4 weeks after the intervention
Method of measurement
Using Extra-intestinal symptoms severity scale questionnaire

2

Description
Quality of life in patients with irritable bowel syndrome
Timepoint
It is measured one day before the intervention and 4 weeks after the intervention
Method of measurement
Using a quality of life questionnaire for patients with irritable bowel syndrome

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this study are given an intramuscular injection of vitamin D. Its dose is 300,000 units. After 4 weeks of injection, patients' quality of life and the degree of gastrointestinal symptoms and irritable bowel syndrome are measured.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir al-Mo'menin Hospital in Arak

Full name of responsible person
Mohammad Reza Rouhani

Street address
Arak, Sardasht Square, Amir Al-Momenin Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Arak University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Leila Savarsfly

Position
Residency

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Residency

Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable