

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

+98 86 3417 3502

##### Email address

jamal.amri71@gmail.com

##### 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

Arak 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

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3601

**Email**

it-amiralmomenin@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Alireza Kamali

**Street address**

Arak University of Medical Sciences, Basij Square

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3645

**Email**

research@arakmu.ac.ir

**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

**Street address**

Arak University of Medical Sciences, Basij Square

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3601

**Email**

Leila.saavar@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Rouhani

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Arak University of Medical Sciences, Basij Square

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3601

**Email**

mohmadreza.rohani@yahoo.com

## Person responsible for updating data

### 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

**Street address**

Arak University of Medical Sciences,Basij Square

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3601

**Email**

name@domian.com

**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