# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 May 2026

## The effects of cholecalciferol, soy isoflavones, and co-administration of them versus placebo on pain, flatulence and quality of life in patients with irritable bowel syndrome

## Protocol summary

**Summary**

Fasting blood specimens were taken from the patients with IBS that have inclusion criteria. First, the objectives and method of study will be explained to the patients and informed consent form was taken from them. They will be divided into 4 groups by an adjusted randomized blocking and the clinical outcomes, quality of life, emotional stress questionnaires will be completed before and after intervention. During 6 weeks, they will receive 2 capsules of soy isoflavones per day, 50000IU vitamin d biweekly in addition to the other placebo form, both of them and placebo of both. At the end,body mass index ( BMI), serum TNF-Alpha, TAC, gene expression of GATA3, ROR gamma, FOXP3 in lymphocytes and gut permeability will be measured. The quantity of polymorphisms of vitamin D and estrogen receptors will be determined.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013112915582N1**
Registration date: **2014-01-03, 1392/10/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2014-01-03, 1392/10/13

**Registrant information**

**Name**

Mahsa Jalili

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2236 0657

**Email address**

jalili.mah@sbmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

National Nutrition and Food Technology Institute
Digestive Disorders Research Institute

**Expected recruitment start date**

2013-12-22, 1392/10/01

**Expected recruitment end date**

2014-03-21, 1393/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of cholecalciferol, soy isoflavones, and co-administration of them versus placebo on pain, flatulence and quality of life in patients with irritable bowel syndrome

**Public title**

The effects of cholecalciferol and soy isoflavones in irritable bowel syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: age 18-75 yrs; patients with Irritable Bowel Syndrome (IBS) according to ROME III criteria; BMI 18-25; no intestinal organic diseases; no intestinal infection; no history of chronic gastrointestinal and colorectal diseases; no intestinal major surgery; no

regular use of antibiotics, anti-constipation and anti-diarrhea, immune suppressors, metocloperamide, cisaperide, difenoxilate, opium and non-steroidal anti-inflammatory drugs; no pregnancy and lactation; not athlete or bed rest; no history of breast cancer in herself or her family; no severe psychosis Exclusion criteria: use of soy isoflavones or vitamin D one year before the study; use of soy milk or soy nuts during study; diet changes during study; use of artificial sweetener 2 days before study; no desire to complete the study; adverse effect of supplement; pregnancy during study

**Age**
From **18 years** old to **75 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **100**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
National Nutrition and Food Technology Institute

**Street address**
Nutrition Faculty of Shahid Beheshti University of Medical Sciences, No. 7, West Argavan Avenue, Shahid Farahzadi Boulevard, Qods Subcity, Tehran

**City**
Tehran

**Postal code**

**Approval date**
2013-11-25, 1392/09/04

**Ethics committee reference number**
050459

## 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**
Clinical Outcomes (pain, flatulence, diarrhea, constipation )

**Timepoint**
before and after the 6 weeks

**Method of measurement**
IBS validated Module according to ROME-III criteria

## Secondary outcomes

### 1

**Description**
gut permeability

**Timepoint**
before and after 6 weeks

**Method of measurement**
The fecal serin protease

### 2

**Description**
Antioxidant status

**Timepoint**
before and after 6 weeks

**Method of measurement**
Serum total antioxidant capacity

### 3

**Description**
inflammation status

**Timepoint**
before and after 6 weeks

**Method of measurement**
Serum tumor necrosis factor-alpha

## Intervention groups

### 1

**Description**
Group A receiving Supplement in form of 50000 IU cholecalciferol biweekly for 6 weeks in addition to 40 milligram placebo capsules similar to soy isoflavones including starch 2 capsules per day for 6 weeks

**Category**
Treatment - Drugs

### 2

**Description**

Group B receiving Supplement in form of 40 milligrams soy isoflavones (diadzein, genstein, glycetin) per day (2 capsules of 20 milligrams) for 6 weeks in addition to supplement of cholecalciferol (vitamin D3) biweekly for 6 weeks

**Category**

Treatment - Drugs

**3**

**Description**

Group C receiving Placebo in similar form of cholecalciferol supplement biweekly for 6 weeks in addition to 40 milligrams placebo in similar form of soy isoflavones including starch for 6 weeks

**Category**

Treatment - Drugs

**4**

**Description**

Group D receiving oral Placebo in similar form to soy isoflavones (diadzein, genstein, glycetin) supplement including starch (2 capsules per day) for 6 weeks in addition to 50000 IU cholecalciferol supplement biweekly for 6 weeks

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Gastrointestinal Clinics of Tehran University of Medical Sciences

**Full name of responsible person**

Mahsa Jalili

**Street address**

Digestive Diseases Research Institute, Tehran University of Medical Sciences, Shariati Hospital, North Kargar Avenue, Tehran

**City**

Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

National Nutrition and Food Technology Institute

**Full name of responsible person**

Dr Fateme Mohammadi Nasr abbadi

**Street address**

Nutrition Faculty, Shahid Beheshti University of Medical Sciences,No. 7, West Argavan Avenue, Farahzadi Boulevard, Qods Subcity, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

National Nutrition and Food Technology Institute

**Proportion provided by this source**

**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*

**2**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences, Digestive Diseases Research Institute

**Full name of responsible person**

Dr. Reza Malek zadeh

**Street address**

Shariati Hospital, Jalal-al ahmad Avenue, North Kargar Avenue, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran University of Medical Sciences, Digestive Diseases Research Institute

**Proportion provided by this source**

**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**

Nutrition Faculty of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahsa Jalili

**Position**

PhD candidate of Nutrition Sciences

**Other areas of specialty/work**

**Street address**

No.7, West Argavan Avenue, Farahzadi Boulevard,

Qods Subcity, Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 2235 7483

**Fax**

**Email**

jalili.mah@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Nutrition Faculty of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Azita Hekmatdoost

**Position**

PhD of Nutrition Sciences, MD

**Other areas of specialty/work**

**Street address**

Nutrition Faculty of Shahid Beheshti University of Medical Sciences, No.7, West Argavan Avenue, Farahzadi Boulevard, Qods Subcity, Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 2235 7483

**Fax**

**Email**

a_hekmat2000@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Nutrition Faculty of Shahid University of Medical Sciences

**Full name of responsible person**

Mahsa Jalili

**Position**

PhD candidate of Nutrition

**Other areas of specialty/work**

**Street address**

Nutrition Faculty of Shahid Beheshti University of Medical Sciences, No.7, West Argavan Avenue, Shahid Farahzadi Boulevard, Qods Subcity, Tehran

**City**

Tehran

**Postal code**

**Phone**

+98 21 2387

**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*