

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Low FODMAPs diet vs. general dietary advice improves clinical response in patients with IBS-D: a randomized controlled trial

#### Protocol summary

##### Summary

This study is designed to investigate the effect of low FODMAP diet vs. current dietary treatment, general dietary advices, on the clinical response and quality of life in patients with diarrhea subtype of IBS (IBS-D), and will be performed as a randomized (Blocked randomization), single blind trial at one medical center in Kerman, Iran; the studied groups include a group taking the low FODMAP diet and another group taking general dietary advices, each of which consisting of 55 IBS-D patients, based on the ROM-III criteria. none of the patients was not aware about types of intervention. Inclusion criteria including: IBS with diarrhea subtype (Bristol Stool Form Scale  $\geq 5$ ) and age 20-60 years old. exclusion criteria including: having a confounder medical condition such as celiac disease, inflammatory bowel disease (IBD) or presence of cardiovascular, liver, kidney, neurologic diseases, diabetes and thyroid disorders, consumption of  $\omega$ -3 FAs and other nutritional supplements in the last 3 months, pregnancy in during the study. The use of effective drugs against IBS such as drugs affecting GI motility is not allowed Gastrointestinal symptoms and bowel habit status will be evaluated using a symptom severity scoring system (IBS-SSS) and Bristol stool form scale (BSFS) pre and post intervention. the duration of intervention will be 6 weeks. Primary outcomes for this study is gastrointestinal symptoms severity and bowel habit status and secondary outcome is quality of life.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017093033308N1**

Registration date: **2017-10-09, 1396/07/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-09, 1396/07/17

##### Registrant information

###### Name

Vahideh behrouz

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3251 0380

###### Email address

vh.behrouz@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2017-11-22, 1396/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Low FODMAPs diet vs. general dietary advice improves clinical response in patients with IBS-D: a randomized controlled trial

##### Public title

Low FODMAPs diet in patients with IBS-D

##### Purpose

Treatment

## Inclusion/Exclusion criteria

. Inclusion criteria for participants' enrollment were IBS with diarrhea subtype (Bristol Stool Form Scale  $\geq$  5) and age 20-60 years old. Exclusion criteria were having a confounder medical condition such as celiac disease, inflammatory bowel disease (IBD) or presence of cardiovascular, liver, kidney, neurologic diseases, diabetes and thyroid disorders, consumption of  $\omega$ -3 FAs and other nutritional supplements in the last 3 months, pregnancy in during the study. The use of effective drugs against IBS such as drugs affecting GI motility was not allowed, but antidepressants drugs were allowed on a stable dose for the last 3 months before inclusion.

### Age

From **20 years** old to **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **110**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

The patients will stratified according to age, sex and gastrointestinal symptoms severity

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

##### Street address

Shafa Crossroad; Jomhuri Boulevard; Kerman, Iran

##### City

Kerman

##### Postal code

##### Approval date

2010-09-23, 1389/07/01

##### Ethics committee reference number

IR.KMU.REC.1395.98

## Health conditions studied

### 1

#### Description of health condition studied

Irritable bowel syndrome

#### ICD-10 code

K58.0

#### ICD-10 code description

Irritable bowel syndrome with diarrhoea

## Primary outcomes

### 1

#### Description

gastrointestinal symptoms

#### Timepoint

3 weeks

#### Method of measurement

questionnaire

### 2

#### Description

bowel habit status

#### Timepoint

6 weeks

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

quality of life

#### Timepoint

6 weeks

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Low FODMAP diet

#### Category

Treatment - Other

### 2

#### Description

general dietary advices

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Afzalipour hospital

**Full name of responsible person**

Dr. Zahedi Mohammad Javad

**Street address**

**City**

Kerman

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research; Kerman University of Medical Sciences

**Full name of responsible person**

Pardakhti Abbas

**Street address**

Shafa Crossroad; Jomhuri Boulevard; Kerman

**City**

Kerman

**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; Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Vahideh Behrouz

**Position**

Ms.c. 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*