

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 ≥ 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 ω -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 ω -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 Committe 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

Other areas of specialty/work

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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