

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of almond fruit (*Prunus amygdalus L.*) on severity of symptoms in irritable bowel syndrome

Protocol summary

Summary

The aim of this study is to assess the effectiveness of almond on improvement of symptoms in IBS patients. Criteria for entering the study: Criteria for entering the study are the presence of Rome III cirrhosis, which include: pain; recurrent abdominal discomfort for at least three days a month in the last three months, with the elimination of two of the following: defecation with bowel movements; The onset of symptoms with a change in the frequency of bowel movements; the onset of symptoms along with a change in the stool shape; withdrawal criteria for patients who did not take the medicine on a regular basis; patients who did not complete the assessment form completely. The study candidates are patients who refer to Afzalipour hospital from October 2016 to October 2017. A number of 50 patients were randomized into two groups of intervention which receives almond granules (40g/day) for 20 consecutive days and placebo group which receive equal wheat flour granules daily for 20 days. the patients will be evaluated through a data assessment form respect to symptoms of abdominal pain intensity and consequence, bowel movement frequency and bloating severity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070234861N1**

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

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-09, 1396/07/17

Registrant information

Name

Fariba Sharififar

Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Kerman University of Medical Sciences

Expected recruitment start date

2016-12-20, 1395/09/30

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of almond fruit (*Prunus amygdalus L.*) on severity of symptoms in irritable bowel syndrome

Public title

effect of almond fruit in IBS patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Criteria for entering the study are the presence of Rome III cirrhosis, which include: pain; recurrent abdominal discomfort for at least three days a month in the last three months, with the elimination of two of the following: defecation with bowel movements;

The onset of symptoms with a change in the frequency of bowel movements; the onset of symptoms along with a change in the stool shape; Exclusion criteria withdrawal criteria for patients who did not take the medicine on a regular basis; patients who did not complete the assessment form completely

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy

Street address

Tahmase Abad Crossroads, Ibn Sina Avenue

City

kerman

Postal code

7619813159

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

IRKMUREC139601195

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

pain location

Timepoint

20 day

Method of measurement

Data validation form

2

Description

pain consequence

Timepoint

days 0 and 20

Method of measurement

data evaluation form

3

Description

pain consequence

Timepoint

days 0 and 20

Method of measurement

data evaluation form

4

Description

pain intensity

Timepoint

days 0 and 20

Method of measurement

data evaluation form

Secondary outcomes

1

Description

Buttal in daily functio

Timepoint

20 day

Method of measurement

Data validation form

2

Description

.pain intensity

Timepoint

days 0 and 20

Method of measurement

data evaluation form

3

Description

analgesic drug taking

Timepoint

days 0 and 20

Method of measurement

data evaluation form

Intervention groups

1

Description

The intervention group contains 25 patients treated with sachets containing 40 grams of almond granules daily for 20 days

Category

Treatment - Drugs

2

Description

Placebo group received equal amount of wheat flour granules daily for 20 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Dr. Fariba Sharififar

Street address

Imam Highway Afzalipour Hospital

City

kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences, Vice Chancellor of Research

Full name of responsible person

Dr. Mehdi Ansari

Street address

Faculty of Pharmacy

City

Kerman

Grant name

Grant code / Reference number

95/00500

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

Yes

Title of funding source

Kerman University of Medical Sciences, Vice Chancellor of Research

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

Afzalipour Hospital

Full name of responsible person

Mahnaz Azimipour

Position

medical student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Mahnaz Azimipour

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Phone

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