Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of almond fruit (Prunus amygdalus L.) on sevirity 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 sevirity 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 consequency
Timepoint
days 0 and 20
Method of measurement
data evaluation form

3

Description
pain consequency
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 containsf 25 patients treated with sachets containing 40 grams of almond granules daily for 20 days

Category

Treatment - Drugs

2

Description

Placebo group recieved equal amount of wheat flour granul 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 Chanellor 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 Chanellor 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

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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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Person responsible for updating data

Contact

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Medical School

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Mahnaz Azimipour

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Medical Student

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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