

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The Efficacy of Habb-e Jalinous and Psyllium compared with Placebo and Psyllium on adult functional constipation: A double blinded clinical trial

Protocol summary

Study aim

Effect of Jalinous tablet in the treatment of functional constipation symptoms

Design

About 126 patients refer to GI Clinic of Imam Khomeini Hospital, enroll the study. It is double-blinded clinical trial. They will randomly divide into 2 groups: Jalinous and Psyllium; Placebo and Psyllium by computer-based randomization method. Questionnaires will be asked based on ROME IV, ODS and Bristol Stool Scale, Initially, day 14 and 28. Intervention time is 1 month

Settings and conduct

Patients having functional constipation according to Rome IV Criteria refer to GI Clinic of Imam Khomeini Hospital of Tehran University

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-50 years, Ability to understand and answer questions, Qualified for ROME IV functional constipation, Confirmed functional constipation diagnosis by GI specialist, Non-pregnancy and lactation, Completing consent form. Exclusion criteria: Diseases may lead to hospitalization or medication, Use other laxatives in study more than 2 times a week, Addiction, Alarm signs, Severe side effect, Patient's unwillingness to continue, No drug use more than 7days, Have a history of allergy to drug components, Use of drugs influence on bowel motility, Previous history of GI surgery

Intervention groups

Patients randomly divide into 2 groups: Jalinous tablet and Psyllium sachet; Placebo tablet and Psyllium sachet. They take a Psyllium sachet in a glass of water every morning and 2 Jalinous tablet with warm water before bed; instead, the other; 2 Placebo tablet with warm water at bed

Main outcome variables

Changes in severity of functional constipation symptoms will be measured based on ROME IV and ODS questionnaire: frequency of bowel movements, changes in frequency of hard stool, incomplete defecation, use of

manual maneuvers, straining and stool consistency based on Bristol at 0,14, 28 days of intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190312043025N1**

Registration date: **2020-01-20, 1398/10/30**

Registration timing: **retrospective**

Last update: **2020-01-20, 1398/10/30**

Update count: **0**

Registration date

2020-01-20, 1398/10/30

Registrant information

Name

shahdis barimani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4436 7873

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sbarimani@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-22, 1397/11/02

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Habb-e Jalinous and Psyllium compared with Placebo and Psyllium on adult functional constipation: A double blinded clinical trial

Public title

The Efficacy of Jalinous tablet compared with Placebo on adult functional constipation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18 to 50 years old Ability to understand, speak and answer the questions Qualified for ROME IV functional constipation Confirmed functional constipation diagnosis by gastrointestinal specialist Non-pregnancy and lactation Complete the consent form

Exclusion criteria:

New disease that may lead to hospitalization or new medications Use other laxatives when studying more than 2 times a week Drug Addiction Alarm signs (rectal bleeding, fever, loss of appetite, weight loss, ...) Incidence of severe side effect of the study drug The patient's unwillingness to continue participating in the study for any reason No regular drug use (more than 7 days) Have a history of allergy to aloe Vera, rose, Indian Jalap and mastic Recent use of antacid, anticholinergic, anti Parkinson, anti psychotic and tricyclic antidepressants, anticonvulsants, antidepressants, diuretics and calcium blockers, iron products, opioids, calcium, prophylaxis Contains progesterone Previous history of any abdominal and gastrointestinal surgery

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients eligible for inclusion criteria, by using balanced the block randomization with Excel computer software, will randomly be divided into two groups: A: Jalinous tablet and Psyllium sachet, B: Placebo tablet and Psyllium sachet

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs will be packaged in two groups (A and B) by a

person whom won't participate in study. Patients, physicians and all person that participate in collecting data would be blinded. After analysis, the contents of the package will be announced.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Science, Imam Hussein Square, Zand street

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.SUMS.MED.REC.1397.471

Health conditions studied**1****Description of health condition studied**

Functional Constipation

ICD-10 code

K59.00

ICD-10 code description

Constipation, unspecified

Primary outcomes**1****Description**

Changes in frequency of defecation

Timepoint

Before intervention and after 14 and 28 days of treatment

Method of measurement

Symptoms of constipation will be assessed using an investigator generated questionnaire based on the Rome IV criteria and ODS questioner. We will evaluate the frequency of defecation as per week.

2

Description

Changes in incomplete defecation and evacuation

Timepoint

Before intervention and after 14 and 28 days of treatment

Method of measurement

Symptoms of constipation will be assessed using an investigator generated questionnaire based on the Rome IV criteria and ODS questioner. We will evaluate the percent of incomplete defecation from 0-100 (never to always)

3

Description

Changes in straining

Timepoint

Before intervention and after 14 and 28 days of treatment

Method of measurement

Symptoms of constipation will be assessed using an investigator generated questionnaire based on the Rome IV criteria and ODS questioner. We will evaluate the percent of straining from 0-100 (never to always).

4

Description

Changes in using of manual maneuver

Timepoint

Before intervention and after 14 and 28 days of study

Method of measurement

Symptoms of constipation will be assessed using an investigator generated questionnaire based on the Rome IV criteria and ODS questioner. We will evaluate the percent of manual maneuver from 0-100 (never to always).

5

Description

Changes of hard stool

Timepoint

Before intervention and after 14 and 28 days of study

Method of measurement

Symptoms of constipation will be assessed using an investigator generated questionnaire based on the Rome IV criteria and ODS questioner. We will evaluate the percent of hard stool from 0-100 (never to always)

Secondary outcomes

1

Description

Changes in stool consistency

Timepoint

According to Bristol stool scale, at baseline, week 2 and 4

Method of measurement

The Bristol stool scale will be used to specify the stool forms: types 1 and 2 considered as hard, 3 and 4 as

normal and 5 to 7 as loose stool. Overall improvement in each symptoms will be assessed and categorized as complete or partial improvement, same and worse.

2

Description

Overall self-reported improvement in symptoms after treatment

Timepoint

At the end of intervention

Method of measurement

After intervention based on patients attitude, Using the options of: deterioration, unchanged, partial recovery and complete recovery

3

Description

Side effects

Timepoint

At the end of week 2 and 4

Method of measurement

Using the check lists

Intervention groups

1

Description

Intervention group: every morning when fasting, patients using a 10 gram Psyllium granule sachet; manufactured by Dineh company with registration code 6911052432012790 witch made from Plantago Psyllium seed; in a glass of water, and take two Jalinous tablet (Habbe - Rahat), licensed to administer natural, traditional and complementary products No.s-0212-92, containing: mastic, Aloe Vera, Rose, Indian Jalap, with warm water before bed.

Category

Treatment - Drugs

2

Description

Control group: Patients, take a 10 gram Psyllium granule sachet; manufactured by Dineh company with registration code 6911052432012790 witch made from Plantago Psyllium seed; in a glass of water, every fasting morning, and take two Placebo tablets containing starch powder with warm water before bed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Gastrointestinal disease of Imam Khomeini Hospital

Full name of responsible person

Barimani Shahdis

Street address

End of Keshavarz Blvd., Dr.Gharib Street, Imam
Khomeini Hospital Complex

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Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Barimani Shahdis

Position

PhD Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Ghasemi Younes

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Barimani Shahdis

Position

Student of PhD

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available