Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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Iran (Islamic Republic of)
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+98 21 4436 7873
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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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Phone
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Imamhospital@tums.ac.ir
Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
Name of organization / entity
Shiraz University of Medical Sciences
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Barimani Shahdis
Position
PhD Student
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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