

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessing the laxative effect of Laxactive (combination of pesilium and fig powder) compared to placebo in patients with constipation

Protocol summary

Study aim

Assessing the laxative effect of Laxactive (combination of pesilium and fig powder) in patients with constipation

Design

80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table

Settings and conduct

This double blinded study will be performed in private clinic. At base line Patient Assessment of Constipation-Symptoms (PAC-SYM) questionnaire will be completed for each patient. after 2 weeks of intervention with supplement/placebo patients will complete PAC-SYM again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having constipation diagnosed by gastroenterologist based on Rome 3 criteria, Age>18 years, Willing to participate Exclusion criteria: having known kidney disease, having known heart disease, pregnancy or lactation

Intervention groups

Patients will receive 22 gram sachet containing 5 gram pesilium powder, 15 gram fig fruit powder, and 5 gram sorbitol (@Lax active, Sepid Teb) or similar amount of placebo 2 times daily, before lunch and dinner, each time 1 sachet for 2 weeks. Placebo capsule contain maltodextrine.

Main outcome variables

PAC-SYM score changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N23**

Registration date: **2022-07-26, 1401/05/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-26, 1401/05/04**

Update count: **0**

Registration date

2022-07-26, 1401/05/04

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

razeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the laxative effect of Laxactive (combination of pesilium and fig powder) compared to placebo in patients with constipation

Public title

laxative effect of Laxactive (combination of pesilium and fig powder) in patients with constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having constipation diagnosed by gastroenterologist based on Rome 3 criteria Age>18 years Willing to participate

Exclusion criteria:

Pregnancy and lactation Having known kidney disease Having known heart disease

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code (supplement and placebo) at the time of sampling. The following groups of people involved in the trial: participants, Research team including principle investigator, data collectors, and outcome assessors will be blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research Institute

Street address

Hafezi Avenue, Farahzadi Blvd

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1401.022

Health conditions studied

1

Description of health condition studied

constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Gastrointestinal function

Timepoint

Before intervention and after 8 weeks of intervention

Method of measurement

Patient Assessment of Constipation-Symptoms questionnaire score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 22 gram sachet containing 5 gram pesilium powder, 15 gram fig fruit powder, and 5 gram sorbitol (@Lax active, Sepid Teb) two times daily before lunch and dinner for 2 weeks

Category

Treatment - Other

2

Description

Control group: 22 gram sachet of placebo (®Lax active, Sepid Teb) containing maltodextrin two times daily before lunch and dinner for 2 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

private clinic

Full name of responsible person

Soodeh Razeghi Jahromi

Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

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+98 21 2235 7483

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soodehrazeghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sepid Teb company

Full name of responsible person

Roya Pourshaghagh

Street address

No 25, 6th alley, 16 St, Khaled-Estanboli St

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Province

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Postal code

1511765613

Phone

+98 21 2774

Email

info@sepidteb.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sepid Teb company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razghei Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data would be available to public

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

To all

Under which criteria data/document could be used

No other criteria

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document

sending email

Comments