Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
soodehrazeghi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sepid Teb company
Full name of responsible person
Roya Pourshaghaghi
Street address
No 25, 6th alley, 16 St, Khaled-Estanboli St
City
Tehran
Province
Tehran
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
Street address
No. 7, West Arghavan St., Farahzadi Blv., Qods Town
City
Tehran
Province
Tehran
Postal code
4741-19395
Phone
+98 21 2235 7483
Email
soodehrazeghi@gmail.com

Person responsible for scientific 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
Street address
No. 7, West Arghavan St., Farahzadi Blv., Qods Town
City
Tehran
Province
Tehran
Postal code
4741-19395
Phone
+98 21 2235 7483
Email

soodehrazeghi@gmail.com

Person responsible for updating data

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

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

City
Tehran

Province
Tehran

Postal code
4741-19395

Phone
+98 21 2235 7583

Email
soodehrazeghi@gmail.com

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