Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessing the effect of probiotic on adult functional constipation

Protocol summary

Study aim
The aim of this study is to evaluate the effect of synbiotics on constipation severity and stool consistency in adults with functional constipation.

Design
A clinical trial with parallel control and interventional groups, randomized (balanced blocked randomization), is performed on 180 patients.

Settings and conduct
Adult patients with functional constipation referred to Sari gastrointestinal clinics, after obtaining consent, will be asked about their demographic information and the status of primary constipation. patients randomly will receive an A or B package of drugs. Constipation is also recorded in follow-up.

Participants/Inclusion and exclusion criteria
Patients who have functional constipation according to the Rome (III) criterion and do not change their diet from normal during the study and are over 18 years of age are included in the study. Patients with depression, systemic diseases such as diabetes, and inflammatory bowel disease, constipation due to hypothyroidism and hypercalcemia, surgeries such as prostate, resection of the intestine, and spine surgery, recent weight loss, cancer need for colonoscopy, recent use of Laxatives, pregnancy, and lactation, alcohol and opium use, recent steroid use, anticholinergics, iron, and sulfasalazine will be excluded.

Intervention groups
Control group: standard treatment (15 gr of psyllium daily) for 30 days. Intervention group: standard treatment and GeriLact Capsules (zist takhmir, Tehran, Iran) twice daily (half an hour before breakfast and dinner) for 30 days. GeriLact will be continued alone for another 15 days.

Main outcome variables
constipation severity and stool consistency

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200915048726N1**
Registration date: **2022-06-06, 1401/03/16**
Registration timing: **prospective**

Last update: **2022-06-06, 1401/03/16**
Update count: **0**

Registration date
2022-06-06, 1401/03/16

Registrant information

Name
Arash kazemi visri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3337 7176

Email address
arash_6z@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing the effect of probiotic on adult functional

constipation

Public title
Synbiotic effect on adult functional constipation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with functional constipation according to Rome (III) criteria. Patients who do not change their diet during the study. Over 18 years
Exclusion criteria:
Depression systemic diseases such as diabetes, and inflammatory bowel disease Constipation due to hypothyroidism and hypercalcemia Surgeries such as prostate, bowel resection , and spine surgery Recent weight loss cancer Requiring colonoscopy Recent use of laxatives Pregnancy and lactation Alcohol and opium users Recent use of steroids, anticholinergics, antidepressants, iron, statins, cholestyramine, Cox-2 inhibitor, and sulfosalazine
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
To decrease the confounding effects, all participants will be randomly allocated into the control and intervention groups to receive psyllium, the standard treatment (n = 90), or psyllium and Gerilact supplement (n = 90) based on balanced block randomization (allocation 1: 1). Blocks with sizes 2, 4, and 6 are used. Excel software will be used to perform randomization. To conceal the randomization process, closed envelopes are used, which are opened at the patient's visit to minimize the gap between randomization and receiving medication or supplements.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran University of Medical Sciences - Sari Imam educational and medical hospital
Street address
Imam hospital, Razi Ave., Sari Town
City
Sari
Province
Mazandaran
Postal code
4816633131
Approval date
2020-09-23, 1399/07/02
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1399.067

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
Severity of constipation
Timepoint
At the beginning of the study (before the intervention), 15, 30, and 45 days after the beginning
Method of measurement
Wexner constipation Scoring System

2

Description
Stool consistency
Timepoint
At the beginning of the study (before the intervention), 15, 30, and 45 days after the beginning
Method of measurement
Bristol scoring system

Secondary outcomes

1

Description
Side effects
Timepoint
At the beginning of the study (before the intervention), 15, 30, and 45 days after the beginning
Method of measurement

evaluation checklist

2

Description
Remission
Timepoint
At the beginning of the study (before the intervention), 15, 30, and 45 days after the beginning
Method of measurement
Total scores obtained from Wexner and Bristol systems

Intervention groups

1

Description
Control group: standard treatment (15 gr of psyllium daily) for 30 days
Category
Treatment - Drugs

2

Description
Intervention group: standard treatment and GeriLact Capsules (zist takhmir, Tehran, Iran) twice daily (half an hour before breakfast and dinner) for 30 days. GeriLact will be continued alone for another 15 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital - Sari
Full name of responsible person
Arash Kazemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram Ebrahimnejad
Street address
Mazandaran University of Medical Sciences, Valiasr Highway, Joibar three ways, Imam Square
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۴۸۱۵۷۳۳۹۷۱
Phone
+98 11 3448 4800
Email
pebrahimnejad@mazums.ac.ir
Grant name
Grant code / Reference number
8136
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
100
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
Mazandaran University of Medical Sciences
Full name of responsible person
Arash Kazemi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
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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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All data can be shared when participants are not identifiable

When the data will become available and for how long
Ability to access data 6 months after publishing the results

To whom data/document is available
The data will be available to academic researchers and non-academic physicians

Under which criteria data/document could be used
Perform other analyzes and extract more results

From where data/document is obtainable
Please refer to the e-mail address of the corresponding author

What processes are involved for a request to access data/document
Submit a request to the Deputy of research and technology of the University / Refer the request to the relevant author of the project

Comments