

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 sulfasalazine

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

Street address

Imam Khomeini Hospital., Razi Ave

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Sari

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Phone

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Email

arash_6z@yahoo.com

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

City

Sari

Province

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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

Contact

Name of organization / entity

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Full name of responsible person

Arash Kazemi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Subspecialist

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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