Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of non-pharmacological treatment including diet adjustment and increased physical activity in the treatment of functional constipation

Protocol summary

Study aim
Investigating the effect of non-pharmacological treatment (diet adjustment and increased physical activity) in the treatment of functional constipation

Design
Clinical trial without control group (single group), phase 2 on 64 patients.

Settings and conduct
The present study is a clinical trial that will be conducted in Isfahan. Patients' demographic information is first collected by a questionnaire. The severity of constipation in patients at the beginning of the study is measured by a questionnaire based on the Rome III criteria. Patients will then be scheduled to adjust their diet and increase physical activity for 12 weeks. Again, the constipation questionnaires for all patients will be filled in weeks 2, 4, 8, and 12 after the intervention begins, and scoring will be done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having functional constipation based on Rome III criteria; Providing informed written consent to participate in the study. Non-inclusion criteria: Any history of chronic inflammatory disease or structural disease of the gastrointestinal tract; Any serious physical illness or illnesses such as inflammation or malignancy; Any physical problem that prevents from doing physical activity; Addiction to the drug or sleeping pills; History of chronic diseases such as diabetes.

Intervention groups
Patients will be scheduled to adjust their diet and increase physical activity for 12 weeks. Diet adjustment is done by designing a diet containing 3 to 6 grams of fiber and 2 glasses of water or other liquids other than tea on a daily basis and by a nutritionist, as well as according to the daily needs of each person. Activity levels are defined as half an hour of brisk walking daily, which increases heart rate by 50%.

Main outcome variables
Constipation severity score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200601047621N2**
Registration date: **2020-06-23, 1399/04/03**
Registration timing: **prospective**

Last update: **2020-06-23, 1399/04/03**
Update count: **0**

Registration date
2020-06-23, 1399/04/03

Registrant information

Name
Maryam Soheilipour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3729 4502

Email address
maryamsoheilip@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-25, 1399/06/04

Expected recruitment end date
2020-10-24, 1399/08/03

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of non-pharmacological treatment including diet adjustment and increased physical activity in the treatment of functional constipation

Public title

Non-pharmacological treatment of constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having functional constipation based on Rome III criteria Free and informed written consent to participate in the study

Exclusion criteria:

Any history of chronic inflammatory disease or structural disease of the gastrointestinal tract Any serious physical problems or illness such as inflammation or malignancy Any physical problem that prevents from doing physical activity Drug or sleeping pills addiction History of chronic diseases such as diabetes

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No. 8, Hezar Jarib Ave., Daneshgh Blvd., Isfahan

City

Isfahan

Province

Isfehan

Postal code

6719674255

Approval date

2020-05-23, 1399/03/03

Ethics committee reference number

IR.MUI.MED.REC.1399.106

Health conditions studied

1

Description of health condition studied

constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Functional constipation

Timepoint

Weeks 2, 4, 8 and 12 after the intervention begins

Method of measurement

Questionnaire for constipation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The severity of constipation in patients at the beginning of the study is measured by a questionnaire based on Rome III criteria, then patients will be scheduled to adjust their diet and increase physical activity for 12 weeks. Diet adjustment is done by designing a diet containing 3 to 6 grams of fiber and 2 glasses of water or other liquids other than tea on a daily basis and by a nutritionist, as well as according to the daily needs of each person. The rate of activity is defined as half an hour of brisk walking daily, which increases the heart rate by 50%. Again, constipation severity questionnaire will be filled out for all patients at weeks 2, 4, 8, and 12 after the intervention begins.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khorshid Hospital

Full name of responsible person
Maryam Soheilipour

Street address
Khorshid hospital, Ostandari Blvd., Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjoo

Street address
No. 8, Hezar Jarib Ave., Daneshgh Blvd., Isfahan

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+98 31 3729 4079

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haghjoo.sh@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Maryam Soheilipour

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Email
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Web page address

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
The information of this research will be available after deleting the names and details of the patients, through the research deputy of Isfahan University of Medical Sciences. These data include age, sex, duration of illness, and treatment information.
When the data will become available and for how long
Late 2020
To whom data/document is available
Health researchers
Under which criteria data/document could be used
In order to use the information in future research and under the permission of the Vice Chancellor for Research
From where data/document is obtainable
Information will be available through the Research Vice Chancellor of Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
Apply online through the university website and issue a license within about 2 weeks and apply for data access
Comments