

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

the effect of an herbal Formula of Zizifus Jujuba as complementary treatment of elderly functional constipation

Protocol summary

Study aim

The aim of this study is to investigate the effectiveness of a product of jujube fruit, a plant native to Iran with nutritional value and laxative effect in the treatment of chronic constipation in the elderly.

Design

Clinical trial with control group, parallel groups, open label, randomized, phase 3 on 60 patients.

Settings and conduct

Patients over 60 years of age referring to the specialized clinics of Iran University of Medical Sciences located in Tehran, whose functional constipation has been approved by a respected gastroenterologist, will be included in the study. During the 4-week treatment period, the patients will be contacted and reminded by phone twice (once every 3 days).

Participants/Inclusion and exclusion criteria

People over the age of 60 whose functional constipation has been confirmed by a gastroenterology specialist based on Rome IV indicators; Not suffering from metabolic or endocrine diseases and any related organic disease With constipation; No use of alcohol and drugs that cause constipation; No history of allergy to fruit or jujube products or Pirolox powder 5. No history of stomach and intestinal surgery; No severe mental illness, psychiatric disorders and neurological diseases; Having the ability to work Physical; No use of antibiotics in the last two weeks; No symptoms of viral gastroenteritis in the last 2 weeks; No malignancy; No abnormal Stool OB, FBS, TFT, Ca tests.

Intervention groups

Elderly over 60 years of age with functional constipation with nutritional and behavioral instructions and jujube product in the amount of two tablespoons every 12 hours on an empty stomach with a glass of warm water and Pirolox powder in the amount of one 20 gram sachet of Pirolox powder dissolved in 1 glass of water and 1 glass 2 Hour after breakfast

Main outcome variables

Number of bowel movements per week

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231022059800N1**

Registration date: **2023-12-07, 1402/09/16**

Registration timing: **prospective**

Last update: **2023-12-07, 1402/09/16**

Update count: **0**

Registration date

2023-12-07, 1402/09/16

Registrant information

Name

Fereshte Fathi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3324 3117

Email address

drfereshtefathi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-18, 1402/09/27

Expected recruitment end date

2024-05-16, 1403/02/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of an herbal Formula of Zizifus Jujuba as complementary treatment of elderly functional constipation

Public title

the effect of an herbal Formula of Zizifus Jujuba on elderly functional constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 60 years, when the presence of functional constipation based on Roman IV indicators has been confirmed by a respected gastroenterologist.

Exclusion criteria:

History of allergy to jujube fruit or jujube product or pidrolox powder. Use of anti-Parkinson drugs, anti-psychotics, tricyclic antidepressants, anti-convulsants, anti-cholinergics, anti-spasms, anti-neoplastic, calcium blockers, 5HT antagonists, iron products. Alcohol and drug abuse. Suffering from severe mental illness and psychiatric disorders. Suffering from neurological diseases such as multiple sclerosis, Parkinson's, progressive systemic sclerosis, spinal cord injury, stroke. Suffering from a metabolic disease such as uncontrolled diabetes, hypothyroidism, hypercalcemia, pheochromocytoma, and any organic disease related to constipation, severe asthma, and bronchitis. Cardiac and hematological patients in case of taking drugs that cause constipation, including calcium blockers, furosemide, iron products, opioids. Inability to do physical activity and having special medical conditions such as inability to move. History of intestinal or stomach surgery, ostomy. History of malignancy and cancer. Kidney and liver failure. Endoscopy, colonoscopy, and radiology report in the last 5 years that has any abnormality and malignancy or IBD. Stool has abnormal OB, FBS, TFT, Ca. Viral gastroenteritis symptoms in the last two weeks.

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **30**

30 people in the intervention group and 30 people in the control group

Randomization (investigator's opinion)

Randomized

Randomization description

The random block method will be used to allocate the samples to two groups. For this purpose, patients will receive number 1 to 60 according to their arrival. The randomization unit will be individually and by number

with blocks of 4 people. The selection of the group type for each person will be done through random allocation 2 statistical software. In order to create a random sequence, codes A and B will be generated from the desired software, where code A will mean the application of the intervention group and code B will mean the application of the control group for each individual. Finally, the codes will be placed in the sealed envelope and the number of each patient will be written on the envelope. As each patient enters, the doctor will open the envelope and apply the desired treatment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The study is conducted as an open label. Because the pharmaceutical forms are different and the two drugs are completely different in appearance, packaging, taste and way of consumption

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Mazandaran University of Medical Sciences

Street address

Ethic committee of Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

48168-95474

Approval date

2023-10-24, 1402/08/02

Ethics committee reference number

IR.MAZUMS.REC.1402.439

Health conditions studied

1

Description of health condition studied

Functional constipation of the elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Number of bowel movements per week

Timepoint

Before the start of the intervention (beginning of the intervention) and days 28, 21, 14, after the intervention

Method of measurement

Asking the patient through a questionnaire

Secondary outcomes

1

Description

Feeling of incomplete emptying after defecation

Timepoint

Before the start of the intervention (beginning of the intervention) and days 28, 21, 14, after the intervention

Method of measurement

Questionnaire and questions from the patient

2

Description

number of times of manual maneuver in defecation

Timepoint

Before the start of the intervention (beginning of the intervention) and days 28, 21, 14, after the intervention

Method of measurement

Questionnaire and questions from the patient

3

Description

consistency of stool

Timepoint

Before the start of the intervention (beginning of the intervention) and days 28, 21, 14, after the intervention

Method of measurement

Questionnaire and questions from the patient

4

Description

the quality of life

Timepoint

Before the start of the intervention (beginning of the intervention) and days 28, 21, 14, after the intervention

Method of measurement

Quality of life questionnaire for functional constipation patients

Intervention groups

1

Description

Intervention group: Intervention group: Jujube-based traditional medicine product, two tablespoons every 12 hours on an empty stomach with a glass of warm water, for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: A 20 gram sachet of Pidrolox powder is dissolved in 1 glass of water and taken 1 glass daily 2 hours after breakfast for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul Akram Hospital clinic

Full name of responsible person

Fereshte Fathi

Street address

Tehran, Sattar Khan, Kh. Niayesh, Corner of Mansoori Street, Rasul Akram Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saidi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

70

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

Assie Jokar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Persian Medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available