

# 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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#### **Province**

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#### **Email**

Drfereshtefathi@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Mazandaran University of Medical Sciences

#### **Full name of responsible person**

Dr Majid Saidi

#### **Street address**

Deputy of Research and Technology Mazandaran University of Medical Sciences, Moalem Ave., Moalem Square

#### **City**

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#### **Province**

Mazandaran

#### **Postal code**

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#### **Email**

pajhooheshi@mazums.ac.ir

#### **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

**Street address**

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

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

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**Other areas of specialty/work**

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Fereshte Fathi

**Position**

Persian Medicine Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

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**City**

Sari

**Province**

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**Postal code**

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**Email**

Drfereshtefathi@gmail.com

**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