

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of Ficus carica and Juglans regia product on the treatment of functional Constipation of older Adults: A double blind randomized clinical trial

#### Protocol summary

##### Study aim

The present study seeks to investigate the effect of Ficus carica and Juglans regia product on the treatment of functional constipation of older adults.

##### Design

This is a clinical trial research with pre-test, post-test, one-month follow-up and control group. There are parallel groups of 90 participants that we will randomly divide the clients into two groups (45 in the experimental group and 45 in the control group).

##### Settings and conduct

This is a randomized clinical trial study in which the double blind method will be used. Therefore we refer to Imam Reza Medical Research & Training Hospital of Tabriz and by using the convenience sampling method, people with discomfort and complaints of constipation are suggested to participate in the study. We offer free treatment to satisfy the clients to participate in the research.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Strain in more than 3 times a week, hard or bullet-like stool in more than 3 times a week, feeling of incomplete emptying in more than 3 times a week, feeling of obstruction or anorectal obstruction in more than 3 times a week, need for manual maneuvers To facilitate defecation in more than 3 times a week, Spontaneous bowel movements less than 3 times a week  
Exclusion criteria: dissatisfaction to participate in the study, intolerance to taking drugs, possible complications (in the form of nausea, vomiting, severe abdominal pain, allergic complications, etc.), incorrect use of drugs

##### Intervention groups

In the intervention group, each patient is given 15 cc of fig and walnut syrup one hour before bedtime for two consecutive weeks. For the control group, each patient is given 15 cc of lactulose syrup (as a placebo) one hour before bedtime for two consecutive weeks.

#### Main outcome variables

Constipationm Stool type, Gastrointestinal pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200714048108N1**

Registration date: **2020-09-19, 1399/06/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-19, 1399/06/29**

Update count: **0**

##### Registration date

2020-09-19, 1399/06/29

##### Registrant information

##### Name

Saeed Jodi Khajeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3380 8848

##### Email address

saeedjodi1348@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-05, 1399/06/15

##### Expected recruitment end date

2021-02-13, 1399/11/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effect of Ficus carica and Juglans regia product on the treatment of functional Constipation of older Adults: A double blind randomized clinical trial

**Public title**  
Effect of Ficus carica and Juglans regia product on the treatment of functional Constipation of older Adults

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Forcing in more than more than 3 times a week Hard or bullet-like stools in more than 3 times a week Feeling of incomplete emptying in more than 3 times a week Feeling of anorectal obstruction or cramping in more than 3 times a week Need for manual maneuvers to facilitate defecation in more than 3 times a week Spontaneous bowel movements less than 3 times a week  
**Exclusion criteria:**  
Dissatisfaction to participate in the research Intolerance to taking drugs Possible side effects (in the form of nausea, vomiting, severe abdominal pain, allergic reactions, etc.) Improper use of medication

**Age**  
From **55 years** old to **85 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Block randomization will be done using www.randomization.com to assign equal participants in each group (1:1 allocation ). An independent researcher will make random allocation cards using computer-generated random numbers. he will keep the original random allocation sequences until analysis time. Another researcher will measure the patients outcome and he will not know the allocation.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The Gastroenterologist will be aware of the research topic and will perform therapeutic interventions. He codes the patients and refers them to a his colleague to check the patient's stomachs and record the relevant criteria based on the same code. The patients will be tested in the same condition and given the same syrup (Syrups that are the same in color, smell and

appearance), but they will not be aware from the type of medicine. Accordingly, this study will be a double-blind study.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

University Street, 3rd Floor, Central Building, Tabriz University of Medical Sciences, Iran

##### City

Tabriz

##### Province

West Azarbaijan

##### Postal code

5166614766

#### Approval date

2020-05-18, 1399/02/29

#### Ethics committee reference number

IR.TBZMED.REC.1399.161

## Health conditions studied

### 1

#### Description of health condition studied

Constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

Constipation

## Primary outcomes

### 1

#### Description

Gastrointestinal pain

#### Timepoint

Painless stools was measured at the beginning of the study (before the intervention), after the last treatment session, and 30 days (one month) after the last treatment session.

#### Method of measurement

General Mizaj questionnaire

## 2

### **Description**

Constipation

### **Timepoint**

Assessing constipation was measured at the beginning of the study (before the intervention), after the last treatment session, and 30 days (one month) after the last treatment session.

### **Method of measurement**

General Mizaj questionnaire

## 3

### **Description**

Stool type

### **Timepoint**

Stools with less stiffness intervention), after the last treatment session, and 30 days (one month) after the last treatment session.

### **Method of measurement**

General Mizaj questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: For each patient is given 15 cc of fig and walnut syrup one hour before bedtime for two consecutive weeks

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: For the control group, each patient is given 15 cc of lactulose syrup (as a remedy for constipation) one hour before bedtime for two consecutive weeks.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Medical Research & Training Hospital of Tabriz

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

Mostafa Araj khodaei

##### **Street address**

University Street, Tabriz University of Medical Sciences, Iran

##### **City**

Tabriz

#### **Province**

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5166614756

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mostafaa33@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Tabriz University of Medical Sciences

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

Dr Mohmmad Samiei

##### **Street address**

University Street, 3rd Floor, Central Building, Tabriz University of Medical Sciences, Iran

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##### **Phone**

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##### **Email**

Samiei.moh@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

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

Saeed Jodi Khajeh

##### **Position**

Resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Traditional Medicine  
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University Street, 3rd Floor, Central Building, Tabriz  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Dr Mostafa Araj khodaei  
**Position**  
Professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
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**Email**  
saeedjodi1348@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

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

### Title and more details about the data/document

Participant Data File: Because the individual data of the study participants are considered, this study shares some of the data such as information about the main outcomes of the study.

### When the data will become available and for how long

The access period starts 10 months after the results are published.

### To whom data/document is available

The data obtained from this study are only available to researchers working at Tabriz University of Medical Sciences.

### Under which criteria data/document could be used

The data of this research are only permitted for review and meta-analysis studies.

### From where data/document is obtainable

Visit Mr. Saeed Jodi from Tabriz University of medical science, or contact him by email or phone. Phone: 09143081743, Email: saeedjodi1348@gmail.com

### What processes are involved for a request to access data/document

Applicants are required to submit a written request to Mr. Jodi by email (10 months after the publication of the research results). After reviewing the request, the data will be sent to the applicant online via email.

### Comments