

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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+98 41 3380 8848

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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 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

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University Street, Tabriz University of Medical Sciences, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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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Person responsible for updating data

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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