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
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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 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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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