

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the Effect of Combined Fig-Walnut Syrup compared to fig syrup and placebo on functional Constipation and Quality of Life in Pregnant Women: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

To determine the effect of combined fig-walnut syrup on functional constipation and quality of life in pregnant women

Design

A controlled clinical trial with three parallel groups, double blinded, randomized with blocking method, phase three on 90 patients. The randomizer software will be used for randomization.

Settings and conduct

This study will be performed in Al-Zahra and Taleghani hospitals and health Centers of Tabriz. The first group will use the combined fig-walnut syrup, the second group will use fig syrup, and the third group will use placebo, 15 ml every night, half an hour before going to bed, for two weeks. The participants, researcher and data analyst will be blinded. Drugs and placebo will be similar in appearance and will be prepared in similar opaque bottles.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy singleton pregnant women with constipation; Gestational age less than 32 weeks; Being literate in reading and writing. Non-inclusion criteria: Receiving medication for constipation less than one week before the study; Having Intestinal diseases; Having a high-risk pregnancy; Having an addiction to drugs and smoking; Previous allergy to figs or walnuts

Intervention groups

The first intervention group will use the combined fig-walnut syrup, the second intervention group will use fig syrup, and the control group will use placebo, 15 ml every night, half an hour before going to bed, for two weeks.

Main outcome variables

Number of defecation per week; average quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N79**

Registration date: **2023-07-12, 1402/04/21**

Registration timing: **prospective**

Last update: **2023-07-12, 1402/04/21**

Update count: **0**

Registration date

2023-07-12, 1402/04/21

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Triple blinded
Scientific title	Blinding description
Evaluation the Effect of Combined Fig-Walnut Syrup compared to fig syrup and placebo on functional Constipation and Quality of Life in Pregnant Women: A Randomized Controlled Clinical Trial	The participants, researcher and data analyst will be blinded completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and will be prepared in similar opaque bottles.
Public title	Placebo
Effect of combined fig and walnut syrup on constipation	Used
Purpose	Assignment
Treatment	Parallel
Inclusion/Exclusion criteria	Other design features
Inclusion criteria:	Secondary Ids
Healthy singleton pregnant women with constipation Gestational age less than 32 weeks Being literate in reading and writing	empty
Exclusion criteria:	Ethics committees
Receiving medication for constipation less than one week before the study Endocrine disorders (hypothyroidism) Intestinal diseases such as Hirschsprung, intestinal obstruction, colon cancer, intestinal hernia or stricture, inflammatory bowel disease, previous gastrointestinal surgery, spinal abnormalities and anorectal injuries such as fistula according to the person's own statement Having a high-risk pregnancy including diabetes (people with overt diabetes and disturbed GTT and people who have fasting blood sugar higher than normal range in the first trimester tests), high blood pressure, chronic diseases that affect pregnancy such as heart, vascular, lung diseases and according to the person's own statement and the medical record Having an addiction to drugs and smoking Previous allergy to figs or walnuts	1
Age	Ethics committee
From 15 years old to 49 years old	Name of ethics committee
Gender	Ethics committee of Tabriz University of Medical Sciences
Female	Street address
Phase	Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht street, Azadi street
3	City
Groups that have been masked	Tabriz
- Participant - Investigator - Outcome assessor - Data analyser	Province
Sample size	East Azarbaijan
Target sample size: 90	Postal code
Randomization (investigator's opinion)	5138947977
Randomized	Approval date
Randomization description	2023-06-26, 1402/04/05
The participants in the study will be assigned to two intervention groups (recipients of combined fig-walnut syrup, recipient of fig syrup) and a control group (recipient of placebo) using a random block method with a block size of six and with an allocation ratio of 1:1:1. A computerized program (randomizer software) will be used to create the allocation sequence. For allocation concealment, the allocation sequence will be determined by someone not involved in the study. For blinding, drugs and placebo will be provided in the same opaque bottles that numbered sequentially.	Ethics committee reference number
Blinding (investigator's opinion)	IR.TBZMED.REC.1402.271
	Health conditions studied
	1
	Description of health condition studied
	Functional constipation
	ICD-10 code
	K59.0
	ICD-10 code description
	Constipation
	Primary outcomes
	1
	Description
	Number of bowel movements per week
	Timepoint
	Before the intervention, the first, second, third and fourth weeks
	Method of measurement
	Questionnaire of functional constipation

2

Description

Quality of life score

Timepoint

Before starting the intervention, End of the fourth week

Method of measurement

Specific quality of life questionnaire during pregnancy

Secondary outcomes

1

Description

Straining during defecation

Timepoint

In the first, second, third and fourth weeks after the intervention

Method of measurement

Questionnaire of constipation

2

Description

Sensation of incomplete evacuation

Timepoint

In the first, second, third and fourth weeks after the intervention

Method of measurement

Questionnaire of constipation

3

Description

Sensation of anorectal obstruction

Timepoint

In the first, second, third and fourth weeks after the intervention

Method of measurement

Questionnaire of constipation

4

Description

Manual maneuvers to facilitate defecation

Timepoint

In the first, second, third and fourth weeks after the intervention

Method of measurement

Questionnaire of constipation

5

Description

Stool consistency

Timepoint

In the first, second, third and fourth weeks after the intervention

Method of measurement

Questionnaire of constipation

6

Description

Use of magnesium milk

Timepoint

At the end of the intervention

Method of measurement

Checklist

7

Description

First time of elimination of symptoms and improvement in constipation

Timepoint

At the end of the intervention

Method of measurement

Questionnaire of constipation

8

Description

Satisfaction

Timepoint

At the end of the first, second, third and fourth weeks

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group 1: The participants (30 people) in the first group will use the combined fig-walnut syrup every night, half an hour before going to sleep, in the amount of 15 ml, for two weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: The participants (30 people) in the second group will use the fig syrup every night, half an hour before going to sleep, in the amount of 15 ml, for two weeks.

Category

Treatment - Drugs

3

Description

Control group: Participants (30 people) in the control group will use 15 ml of placebo syrup every night, half an hour before going to bed, for two weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Roghayyeh Valizadeh

Street address

Alzahra Hospital, Artesh street

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

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Email

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Web page address

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2

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Roghayyeh Valizadeh

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3

Recruitment center

Name of recruitment center

Community health centers of Tabriz

Full name of responsible person

Roghayyeh Valizadeh

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Parviz Shahabi

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Research Department, third floor, Central
Construction number 2, Tabriz University of Medical
Sciences, Golgasht Street, Azadi Street, Tabriz

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dabirkhanecent@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

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

Roghayyeh Valizadeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available