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

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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

Scientific title
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

Public title
Effect of combined fig and walnut syrup on constipation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy singleton pregnant women with constipation Gestational age less than 32 weeks Being literate in reading and writing

Exclusion criteria:
Receiving medication for constipation less than one week before the study Endocrine disorders (hypothyroidism) Intestinal diseases such as Hirschiprong, 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

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
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.

Blinding (investigator's opinion)
Triple blinded

Blinding description
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.

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
Reaserch department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht street, Azadi street

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2023-06-26, 1402/04/05

Ethics committee reference number
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
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Postal code
5138663134
Phone
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Full name of responsible person
Roghayyeh Valizadeh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Other areas of specialty/work
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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