

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of using sweet almond oil orally and abdominal massage in the treatment of chronic constipation

Protocol summary

Study aim

Determining the effectiveness of oral sweet almond oil and abdominal massage in the treatment of chronic constipation

Design

The present study is a clinical trial with two intervention groups and a control group, with parallel, without blinded and randomized groups on 90 patients. Randomization will be done by lottery method using cards.

Settings and conduct

This study is a randomized clinical trial without blinding. In this study, all patients with constipation referred to the internal clinics of Fasa city are included in the study based on ROME IV criteria

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 60 years, patients who score one or more based on the constipation evaluation scale; Patients who have bowel movements less than three times a week. Exclusion criteria: The patient uses a specific drug that causes constipation; unwillingness to participate in the study for any reason.

Intervention groups

Two intervention groups will participate in this study. Group A (oral consumption of sweet almond oil) and group B (abdominal massage with sweet almond oil)

Main outcome variables

Constipation, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044802N9**

Registration date: **2023-08-25, 1402/06/03**

Registration timing: **prospective**

Last update: **2023-08-25, 1402/06/03**

Update count: **0**

Registration date

2023-08-25, 1402/06/03

Registrant information

Name

Mostafa Bijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 5012

Email address

bizhani_mostafa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of using sweet almond oil orally and abdominal massage in the treatment of chronic constipation

Public title

Effectiveness of using sweet almond oil orally and abdominal massage in the treatment of chronic constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years Patients who score one or more on the constipation evaluation scale Patients who have less than three bowel movements per week

Exclusion criteria:

The patient has taken a special drug that causes constipation Unwillingness to participation in the study for any reason

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

After determining the sample size, it is estimated that there are 90 patients. Patients will be selected via convenience sampling. Then they will be randomly divided into three groups A, B and C. For this purpose, 90 cards will be prepared. 30 cards labeled A (oral consumption of sweet almond oil), 30 cards labeled B (abdominal massage with sweet almond oil) and 30 cards labeled C (control group) will be placed. After labeling, 90 cards were then put in an envelope and each patient was asked to draw out one card randomly. The group of patients will be determined based on the card labels.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Fasa University of Medical Sciences

Street address

Fars province, Fasa city, Ibn Sina square. Fasa University of Medical Sciences. Fasa Iran

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2023-07-30, 1402/05/08

Ethics committee reference number

IR.FUMS.REC.1402.062

Health conditions studied**1****Description of health condition studied**

chronic constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes**1****Description**

Constipation

Timepoint

Before and three days after the intervention

Method of measurement

Constipation Assessment Scale (CAS)

2**Description**

Pain

Timepoint

Before and three days after the intervention

Method of measurement

Pain McGill Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the abdominal massage group with sweet almond oil, abdominal massage training will be done three times a day with 15 ml of sweet almond oil daily for 15 minutes with a depth of 2 to 4 cm for three consecutive days. Patients do the initial session in the presence of the researcher at the clinic, and if the researcher approves, the study will be continued at home and the researcher will follow up by phone.

Category

Treatment - Other

2**Description**

Intervention group: In the oral sweet almond oil group, 5 ml of sweet almond oil will be given to the patients every 8 hours for 3 days, and the researcher will follow up by

phone.

Category

Treatment - Drugs

3

Description

Control group: In the control group, according to common treatment methods, only drug therapy will be given to patients for three days (three times a day) with the diagnosis of an internal specialist.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Hospital

Full name of responsible person

Mostafa Bijani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Akbar Farjad Far

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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

Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After finishing the study and publishing the results, researchers can use the results of this research by requesting the corresponding author. There is no time limit for using the information of this study

When the data will become available and for how long

There is no time limit for using the information of this study

To whom data/document is available

After finishing the study and publishing the results, researchers can use the results of this research by requesting the corresponding author

Under which criteria data/document could be used

After finishing the study and publishing the results, researchers can use the results of this research by requesting the corresponding author. There is no time limit for using the information of this study

From where data/document is obtainable

Dr. Mustafa Bijani. Associate Professor of Nursing Department. Fasa University of Medical Sciences bizhani_mostafa@yahoo.com 09173308451

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

After finishing the study and publishing the results, researchers can use the results of this research by requesting the corresponding author

Comments