

# 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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farjad\_2020@yahoo.com

**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**

Fasa University of Medical Sciences

**Full name of responsible person**

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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**