

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Effect of Abdominal Massage with Olive Oil on the Severity of Constipation in Elderly

Protocol summary

Study aim

Determine the Effect of Abdominal Massage with Olive oil on the severity of Constipation in the Elderly

Design

Single-blind randomized clinical trial, with three groups (intervention, placebo and control), with parallel group

Settings and conduct

This study is a randomized clinical trial and elderly people will be divided into three groups of intervention, placebo and control according to a simple random method. The sample size in each group is 18 people and the research site of the health centers of Gonabad community will be. There will be no intervention for the elderly in the control group. For the intervention group and placebo, massage therapy will be performed once a day for 20 minutes and for 5 consecutive days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Constipation according to Rome III criteria Earn score 7 and above the elderly's daily activities questionnaire Age over 60 years old No-entrance criteria: organic constipation, hypothyroidism, false obstruction of the intestine, cystic fibrosis, neural anomalies, bowel obstruction, in the last month based on the patient's own case and report. use of Constipation-Inducing Drugs such as Calcium and Iron Supplements, Antihistamines, Tricyclic Antidepressants, Anti-acidases in the last month based on patient records and reports. Lesion in the abdomen and a massage position

Intervention groups

For elderly in the intervention group and placebo, massage therapy will be performed once a day for 20 minutes and for 5 consecutive days. There will be no intervention for the elderly in the control group.

Main outcome variables

Severity of constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180221038821N1**

Registration date: **2018-10-19, 1397/07/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-19, 1397/07/27**

Update count: **0**

Registration date

2018-10-19, 1397/07/27

Registrant information

Name

Iman Ghorbany Moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 0576

Email address

ghorbani.i@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Abdominal Massage with Olive Oil on the Severity of Constipation in Elderly

Public title

The Effect of Abdominal Massage with Olive Oil on the Severity of Constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Constipation According to Rome III Criteria Earn score 7 and above the elderly's daily activities questionnaire Age over 60 years old

Exclusion criteria:

Organic Constipation, Hypothyroidism, False Obstruction of the Intestine, Cystic Fibrosis, Neuromuscular Anomalies and Bowel Obstruction in the Last Month based on the Patient's case and report. Use of Constipation-Inducing Drugs such as Calcium and Iron Supplements, Antihistamines, Tricyclic Antidepressants, Anti-acidases in the last month based on patient records and reports. Skin Lesion in the Abdomen and Massage Position

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the patients were selected by objective sampling method and applying the entry criteria. Then they were randomly assigned (coin throwing) in three groups: massage therapy with olive oil, massage therapy with placebo and control.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind the participants, paraffin oil was used instead of olive oil for massage. Also, the person who completed the questionnaire on the quality of constipation was unaware of the allocation of patients in the studied groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Gonabad University of Medical Sciences

Street address

Asian Road Rim, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

96916-47161

Approval date

2017-12-22, 1396/10/01

Ethics committee reference number

IR.GMU.REC.1396.70

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Severity of constipation

Timepoint

Before the intervention and two days after the end of the intervention

Method of measurement

Constipation Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Abdominal massage with olive oil once a day for 20 minutes and for 5 consecutive days

Category

Treatment - Other

2

Description

Intervention group: Abdominal massage with paraffin oil once a day for 20 minutes and for 5 consecutive days

Category

Placebo

3**Description**

Control group: There will be no intervention for the elderly.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Community health centers in Gonabad city

Full name of responsible person

Dr. Iraj Moradi

Street address

Imam Khomeini Avenue, Medical University of Gonabad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Javad Bazeli

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Gonabad, Imam Khomeini Avenue, Medical University of Gonabad

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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

Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Lila Mehrpor

Position

Master's degree in Internal Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Professor

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Lila Mehrpor

Position

Master's degree in Internal Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Gonabad, Imam Khomeini Avenue, Medical University
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Gonabad

Province

Razavi Khorasan

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After receiving the results of the decision for the
publication, I will produce results.

Study Protocol

No - There is not 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

No - There is not 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