

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of abdominal massage on constipation in elderly patients with fracture

Protocol summary

Study aim

The effect of abdominal massage on constipation in elderly patients with fracture in Pursina Hospital of Rasht

Design

A clinical trial with the control group, parallel-group, randomized groups, without blinding, sample size 66 people (intervention of 33, control of 33)

Settings and conduct

This study is a randomized clinical trial. The study population is elderly with fractures hospitalized in the orthopedic department of Pursina Hospital in Rasht, who are suffering from constipation according to the Constipation Assessment Scale. The sample size is estimated based on the statistical formula of 66 people. After determining the elderly who are eligible to enter the study, the samples are randomly divided into two groups, intervention, and control, based on Random allocation software.

Participants/Inclusion and exclusion criteria

Entry criteria: Elderly men and women 60 years and older; Informed consent; Ability to respond to the questionnaire; Hospitalization due to fracture of more than 48 hours; Constipation based on the constipation Assessment Scale. Exit criteria: cognitive problems; History of mental illness, abdominal hernia, colorectal cancer, inflammatory bowel disease (Crohn's disease, IBD), irritable bowel syndrome and laparotomy; Skin lesions in the abdomen.

Intervention groups

In the intervention group, with 20 ml baby oil for 3 consecutive days, twice a day, morning and evening, during a 15-minute abdominal massage is done according to the instructions of the National Health Service.

Main outcome variables

Constipation score in Constipation Assessment Scale; Stool form; Gastrointestinal symptom rating

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190805044438N2**

Registration date: **2020-04-16, 1399/01/28**

Registration timing: **prospective**

Last update: **2020-04-16, 1399/01/28**

Update count: **0**

Registration date

2020-04-16, 1399/01/28

Registrant information

Name

Roya Mansour-ghanaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4256 5058

Email address

r_ghanaei@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-19, 1399/02/30

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of abdominal massage on constipation in elderly patients with fracture

Public title

The effect of abdominal massage on constipation in elderly patients with fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly men and women 60 years and older. Informed consent to participate in the study. Ability to respond to the questionnaire. Hospitalization due to fracture of more than 48 hours in the orthopedic department of the hospital under study. Determining the problem of constipation based on the constipation Assessment scale(CAS) [scoring above 5 on the constipation Assessment scale].

Exclusion criteria:

Cognitive problems, A history of mental illness, abdominal hernia, colorectal cancer, inflammatory bowel disease (Crohn's disease, IBD), irritable bowel syndrome and laparotomy. Skin lesions in the abdomen.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the patients were selected by applying the entry criteria. Then they were randomly assigned, based on Random allocation software, in two groups: massage therapy and control.

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 Guilan University of Medical Sciences

Street address

Deputy of university Research and Technology of the University, Old Bldg (building) School of Health, in front of 17 Shahrivar Hospital, Shahid Siadati Ave, Namjoo St, Rasht

City

Rasht

Province

Guilan

Postal code

4477163485

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.GUMS.REC.1398.525

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Constipation score in Constipation Assessment Scale (CAS)

Timepoint

Before intervention and 3 days after intervention

Method of measurement

Constipation Assessment Scale (CAS)

2

Description

Gastrointestinal symptom rating

Timepoint

Before intervention and 3 days after intervention

Method of measurement

Gastrointestinal Symptom Rating Scale (GSRS)

3

Description

Stool form

Timepoint

Before intervention and 3 days after intervention

Method of measurement

Bristol Stool Form Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Abdominal massage with baby oil produced by Firooz Health Group for 3 consecutive days, twice a day, morning and evening, abdominal massage for 15 minutes with 20 ml of Firooz baby oil (To make it easier to move the hand on the patient's abdomen and Failure to cause discomfort to him), according to the instructions of the National Health Service (NHS) for the patient. This massage consists of 8 steps. 1. Three movements of the lower abdomen to the navel 2. Three movements from both sides of the pelvic to the pubic symphysis In the upper part and the whole abdomen 6. Repeat steps 4 and 5 .7. The horizontal movement of the abdomen from left to right 8. Vibration movements in all these points.

Category

Treatment - Other

2

Description

Control group:No specific intervention by the researcher will be performed on patients in this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Roya Mansour-ghanaei

Street address

Langeroud School of Nursing and Midwifery, Martyr Yaghoub Sheikhi St. leyla kooh, Langeroud, Guilan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohamadreza Naghipour

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Deputy of university Research and Technology of the University, Old Bldg (building) School of Health, in front of 17 Shahrivar Hospital, Shahid Siadati Ave, Namjoo St, Rasht

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Roya Mansour-ghanaei

Position

Assistant Professor, Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Health Sciences

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

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Full name of responsible person

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available