

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effectiveness of abdominal massage on the prevention of gastrointestinal problems in female elderly with stroke admitted to the intensive care

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of abdominal massage on the prevention of gastrointestinal problems in female elderly with stroke admitted to the intensive care units

Design

This study is performed as a randomized, single-blind clinical trial. The study population included female elderly patients admitted to ICU in the Hospital of Khatam. Eligible patients are randomly selected and randomly assigned to test and control groups.

Settings and conduct

The study is done in intensive care units in the Hospital of Khatam in Tehran. An abdominal massage is done according to the instructions of the National Health Service for every patient. The gastrointestinal symptom rating consists will be checked every day. Samplers will be blind to patients 'random allocation of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 60 or older; Definitive diagnosis of stroke; Have consciousness over than 7; Have a stroke for the first time; After a stroke, have been hospitalized for at least one week; Subjects who were being fed intermittently enterally via a nasogastric tube; Recently started on intermittent enteral feeding; Have no contraindication to an abdominal massage; Constipation is based on the constipation Assessment Scale. Exclusion criteria: The patient's or guardian's unwillingness to continue to be involved in the research project for any reason; Physician dissatisfaction, Having received (prokinetic medications, metoclopramide, erythromycin, cisapride, and anticholinergic agents); Make patients NPO for more than 12 hours for laboratory tests; Develop diarrhea more than 3 times a day.

Intervention groups

In the intervention group, Abdominal massage will be done 15 min before nasogastric tube feeding. The

massage session lasts about 15 min. There is no intervention for the control group.

Main outcome variables

Gastrointestinal Symptom

General information

Reason for update

The sample size was written incorrectly, it was corrected

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N23**

Registration date: **2022-04-20, 1401/01/31**

Registration timing: **prospective**

Last update: **2023-01-21, 1401/11/01**

Update count: **1**

Registration date

2022-04-20, 1401/01/31

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of abdominal massage on the prevention of gastrointestinal problems in female elderly with stroke admitted to the intensive care

Public title

The effect of massage therapy on gastrointestinal complications of stroke patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are suffering from constipation following of stroke that will be admitted to the hospital are enrolled in the study

Exclusion criteria:

Age

From **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients to intervention and control groups by random block method

Blinding (investigator's opinion)

Single blinded

Blinding description

The post interventions information is collected by unbiased collaborations of the uninformed patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran Qom Freeway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

Shahed.REC.1400.090

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I66.0

ICD-10 code description

Occlusion and stenosis of middle cerebral artery

2

Description of health condition studied

Constipation

ICD-10 code

K59.00

ICD-10 code description

Constipation, unspecified

Primary outcomes

1

Description

Constipation

Timepoint

Daily

Method of measurement

Bristol stool scale

2

Description

Gastric residual volume

Timepoint

Before every feeding

Method of measurement

Gavag syringe

3

Description

Distension

Timepoint

Daily

Method of measurement

By measurement circumference abdomen

4

Description

Aspiration

Timepoint

Daily

Method of measurement

Determination airway secretion PH and glucose

5

Description

Defecation

Timepoint

Daily

Method of measurement

Number of defecation

6

Description

Severity of constipation

Timepoint

Daily

Method of measurement

CAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Abdominal massage for 3 consecutive days, twice a day, morning and evening, abdominal massage for 15 minutes with 20 ml of baby oil, 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

The control group will receive usual care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Specialty and Subspecialty Hospital of Khatam ol Anbia

Full name of responsible person

Zahra Baseri

Street address

Specialty and Subspecialty Hospital of Khatam ol Anbia, Rashid Yasemi St., Upper than Mirdamad St., Vali Asr St., Tehran, Iran

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1419733141

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Email

info@khatamhospital.org

Web page address

http://www.khatamhospital.org

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahed University

Full name of responsible person

Dr. Shahriar Bijani

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran

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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

Shahed University

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**

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Not applicable

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

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

Title and more details about the data/document

some of the statistical data is available after being unidentifiable

When the data will become available and for how long

The access period is up to after the publication of the results.

To whom data/document is available

Data is available to academic researchers

Under which criteria data/document could be used

Use of information for academic research projects is allowed.

From where data/document is obtainable

Corresponding author

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

Requests for specific information should be sent by email.

Comments