Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 valume

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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http://www.khatamhospital.org

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Dr. Shahriar Bijani
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Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran
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Email
info@shahed.ac.ir
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
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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