Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating abdominal exercises with and without mint extract on the residual volume of the stomach and abdominal distension in patients undergoing enteral nutrition treatment admitted to the intensive care unit

Protocol summary

Study aim
Comparison of the effects of abdominal massage with and without peppermint extract on gastric residual volume and abdominal distension in patients undergoing enteral nutrition admitted to the intensive care unit.

Design
Clinical trial including two parallel, single-blind, randomized groups with 25 patients in each group.

Settings and conduct
All patients undergoing enteral nutrition were hospitalized in the neurosurgery intensive care unit of Firoozgar Hospital in Tehran.

Participants/Inclusion and exclusion criteria
1-Age between 18-65 years. 2-Patients admitted to a special ward with enteral nutrition and use of NGT for gavage 3-A maximum of 3 times since the start of enteral nutrition. 4-Not receiving metoclopramide, cisapride, anticholinergic drugs. 5- No history of radiotherapy and abdominal surgery in the last 6 weeks (due to wounds and damaged tissues in the abdominal area, it may cause problems for the patient due to rupture, infection, etc. due to massage). 6-Level of consciousness ≤7 7-No contraindications to massage such as: cellulitis, abdominal mass, peritonitis, abdominal aneurysm, ascites, diverticulitis, possibility of any thromboembolism in the last year, presence and history of DVT in the last year. 8-Similar reason for hospitalization such as brain injuries, hospitalization in the neurosurgical intensive care unit

Intervention groups
Performing Swedish massage with mint extract in one group and performing Swedish massage without mint extract and examining its effect on the amount of residual volume

Main outcome variables
The effect of performing abdominal massage with peppermint extract compared to abdominal massage without peppermint extract on gastric residual volume in patients undergoing enteral nutrition admitted to the intensive care unit is different.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250514065728N1**
Registration date: **2025-06-09, 1404/03/19**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-09, 1404/03/19**
Update count: **0**

Registration date
2025-06-09, 1404/03/19

Registrant information

Name
marziyeh safari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-22, 1404/03/01

Expected recruitment end date

2025-06-22, 1404/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating abdominal exercises with and without mint extract on the residual volume of the stomach and abdominal distension in patients undergoing enteral nutrition treatment admitted to the intensive care unit

Public title

Investigating abdominal exercises with and without mint extract on the residual volume of the stomach and abdominal distension in patients undergoing enteral nutrition treatment admitted to the intensive care unit

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-65 years Patients admitted to a special ward with enteral nutrition Maximum 3 times since the start of enteral nutrition No receipt of metoclopramide, cisapride, anticholinergic drugs. No history of radiotherapy and abdominal surgery in the last 6 weeks (due to wounds and damaged tissues in the abdominal area, it may cause problems for the patient due to rupture, infection, etc. due to massage) - Level of consciousness ≤7. No contraindications to massage such as: cellulitis, abdominal mass, peritonitis, abdominal aneurysm, ascites, diverticulitis, possibility of any thromboembolism in the last year, presence and history of DVT in the last year Similar reason for hospitalization such as brain injuries, hospitalization in the neurosurgical intensive care unit.

Exclusion criteria:

Having more than two consecutive bouts of vomiting (less than 12 hours) Taking metoclopramide for vomiting Being NPO due to a lab test or surgical procedure lasting more than 12 hours Diarrhea more than 3 times a day Transferring the patient to the ward in less than 3 days

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate participants to the intervention and control groups, a block randomization method with a block size of 6 and equal allocation (1:1:1) will be used. Randomization will be generated using Random Allocation Generator software, and group allocation will be done in a secret manner and by random coding.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are not aware of the massage with mint extract and the massage without mint extract, and they are only explained how to perform the massage and why it is performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zabol University of Medical Sciences

Street address

Block13 and14, Kohestan complex, North ISsargaran street, Book squere, Saadat abad, Tehran, IRan.

City

Tehran

Province

Tehran

Postal code

1981773433

Approval date

2025-01-22, 1403/11/03

Ethics committee reference number

IR.ZBMU.REC.1403.133

Health conditions studied

1

Description of health condition studied

constipation

ICD-10 code

K59.9

ICD-10 code description

Functional intestinal disorder, unspecified

Primary outcomes

1

Description

The effect of Swedish massage with peppermint extract on residual volume in patients undergoing enteral nutrition.

Timepoint

Three days in a row

Method of measurement
Gavage syringe and graduated cups

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Abdominal massage with mint extract In this group, patients admitted to the ICU who are receiving enteral nutrition will receive abdominal massage twice daily. The massage will be performed by a trained nurse for 15 minutes each time using 5% mint extract. The massage will be performed in a circular, clockwise motion and will include the four quadrants of the abdomen. The mint extract used is manufactured by Gol Daru Company and will be used as a topical solution diluted with sweet almond oil in a 1:1 ratio. This intervention will be performed for 3 consecutive days.
Category
N/A

2

Description
Intervention Group 2: Abdominal Massage Without Peppermint Extract In this group, patients will receive abdominal massage twice daily for 15 minutes, similar to intervention group 1, but without the use of peppermint extract. The massage will be performed with a base oil (sweet almond oil), and the massage technique and location will be the same as in the first group. This intervention will also be performed for 3 consecutive days.
Category
N/A

3

Description
Control group: : : No abdominal massage In this group, patients will receive only routine nursing care and common enteral feeding protocols in the ICU, without any additional interventions including massage or the use of topical agents
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Firuzgar Hospital
Full name of responsible person
Marziyeh Safari
Street address
Block13 and14, Kohestan complex, North ISsargaran street, Book squere, Saadat abad, Tehran, IRan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zabol University of Medical Sciences
Full name of responsible person
Bahman Foladi
Street address
Block13 and14, Kohestan complex, North ISsargaran street, Book squere, Saadat abad, 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
Zabol 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
Zabol University of Medical Sciences
Full name of responsible person
Marziyeh Safari
Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Position

student

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Person responsible for updating data

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Position

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data in this trial can be published after participants are de-identified.

When the data will become available and for how long

6 months after publication of the product

To whom data/document is available

Everyone interested in the field of research

Under which criteria data/document could be used

In case of positive research results

From where data/document is obtainable

IranDoc thesis site

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

No special process is required, just search in IranDoc browser

Comments