Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the effect of Swedish abdominal massage and Tensegrity on nasogastric tube complications in patients hospitalized in the intensive care unit

Protocol summary

Study aim

The effects of Swedish abdominal massage and Tensegrity on nasogastric tube complications in patients admitted to the intensive care unit are compared.

Design

The clinical trial has 2 intervention groups and a control group, with parallel groups, three blind, randomized, on 90 patients. R software was used for randomization.

Settings and conduct

In study , massage based on Swedish and Tensegrity principles will be used in the ICU department of Valiasr and Amiralmominin Arak Hospital. The intervention period is 3 days, twice daily for 20 minutes and the interval between two massages is 2 hours. In this way, the patient receives an abdominal massage, then 100 cc of gavage is given, and 2 hours later, the abdominal massage is performed again. The investigated variables are measured and recorded every day before the intervention and 1 hour after the second massage. The patient and the patient's guardian, outcome parameters evaluator and the statistician, are unaware of the studied groups and the type of intervention.

Participants/Inclusion and exclusion criteria

Nasogastric tube feeding, age between 18 and 65 years, no more than 3 times have passed since the start of enteral feeding, no prokinetic drugs, GCS score below 9, no radiotherapy and abdominal surgery in the last 6 weeks, no contraindications to abdominal massage with examination and confirmation Specialist doctor, the absence of any thromboembolism in the last year, the absence and history of DVT in the last year, the absence of problems affecting excretion such as anorectal disorders

Intervention groups

Intervention group(1) Tensegrity massage technique
Intervention group (2) Swedish massage technique
Control group they will not receive only abdominal massage.

Main outcome variables

The amount of food remaining in the stomach, abdominal distension, defecation, ventilator-associated pneumonia, aspiration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230913059429N1**
Registration date: **2023-10-07, 1402/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-07, 1402/07/15**
Update count: **0**

Registration date

2023-10-07, 1402/07/15

Registrant information

Name

Abdollah Abolfathi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-01-19, 1402/10/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of Swedish abdominal massage and Tensegrity on nasogastric tube complications in patients hospitalized in the intensive care unit

Public title
Comparison the effect of Swedish abdominal massage and Tensegrity on nasogastric tube complications in patients hospitalized in the intensive care unit
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Feeding with nasogastric tube Age between 18 and 65 years A maximum of 3 times have passed since the start of digestive feeding Not receiving prokinetic drugs such as: metoclopramide and anticholinergics such as: atropine and laxatives, erythromycin, cisapride Glasgow Coma score below 9 No radiotherapy and abdominal surgery in the last 6 weeks Absence of contraindications to abdominal massage with the examination and approval of a special care physician such as: severe trauma, cellulitis, abdominal mass, peritonitis, abdominal aneurysm, ascites, diverticulitis, spinal cord injury The absence of any thromboembolism in the last year Absence and history of Deep Vein Thrombosis in the last year Absence of problems affecting excretion such as anorectal disorders
Exclusion criteria:
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is done in an easy way based on the conditions of entry into the study and the samples are allocated to the control and intervention groups based on the randomization list provided by the statistician. The randomization list is prepared using R software.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the patient and the patient's guardian, the evaluator who examines the parameters of the outcomes under investigation, and the respected statistician who performs the data analysis, are unaware of the study groups and the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran
City
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Province
Markazi
Postal code
۳۸۱۹۶۹۳۳۶۵
Approval date
2023-08-01, 1402/05/10
Ethics committee reference number
IR.ARAKMU.REC.1402.128

Health conditions studied

1

Description of health condition studied
In patients hospitalized in the intensive care unit
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Gastric Residual Volume
Timepoint
Before the intervention (immediately before the start of abdominal massage) and one hour after the intervention (second massage) during each day separately
Method of measurement
Aspirating stomach contents with a 50 cc gavage syringe

2

Description
Abdominal circumference size

Timepoint
Before the intervention and one hour after the intervention (second massage) during each day separately
Method of measurement
Using a special flexible meter

3

Description
Defecation per day
Timepoint
Every day
Method of measurement
Counting the number of defecation

4

Description
Ventilator associated pneumonia
Timepoint
Immediately before the start of the intervention on the first day and at the end of the third day of the intervention
Method of measurement
Modified Clinical Pulmonary Infection Score

5

Description
Aspiration
Timepoint
Half an hour before the intervention and one hour after the intervention (second massage) during each day separately
Method of measurement
Using pH strips and glucose meters, the pH and glucose of aspirated secretions from the patient's airways are determined.

Secondary outcomes

empty

Intervention groups

1

Description
In the first intervention group, Tensegrity massage technique (5-stage massage) is used, the first stage includes movements such as brushing the skin of the abdominal area, the second stage changes the flexibility of the tracholumbar fascia, the third stage is kneading the skin of the abdominal area, and the fourth stage is impact movements. along the armpit from top to bottom and bottom to top and the last stage includes changing the elastic shape of the muscles in the interstitial spaces. The intervention period is 3 days. These patients receive 20 minutes of abdominal massage intervention twice a day and the interval between Two massages are 2 hours.
Category
Other

2

Description
Intervention group 2: Swedish massage techniques including stroking, Efleurage, kneading, and vibration are used. The intervention period is 3 days. These patients receive 20 minutes of abdominal massage intervention twice a day, and the interval between two massages is 2 hours.
Category
Other

3

Description
Control group: Feeding and gavage of the patient will be done in the same way as other intervention groups, except that they will not only receive abdominal massage.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Kobra Rahzani
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A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak.
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2

Recruitment center
Name of recruitment center
Amir al-Mominin Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
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Abdollah Abolfathi
Position
Critical care master's student
Latest degree
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Person responsible for updating data

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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
"There is no further information".
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
Not applicable