

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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 Amirmominin 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)

Phone

+98 86 3417 3505

Email address

a.abolfathi@arakmu.ac.ir

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

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

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, Eflourage, 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

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak.

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3383 8226

Email

k.rahzani@yahoo.com

2

Recruitment center

Name of recruitment center

Amir al-Mominin Hospital

Full name of responsible person

Kobra Rahzani

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak.

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3383 8226

Email

k.rahzani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmat Pou

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak,
Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@arakmu.ac.ir

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

Full name of responsible person

Abdollah Abolfathi

Position

Critical care master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak,
Markazi Province, Iran

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3524

Email

A.abolfathi@arakmu.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Kobra Rahzani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Phone

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Email

k.rahzani@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Abdollah Abolfathi

Position

Critical care master's student

Latest degree

Bachelor

Other areas of specialty/work

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Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Phone

+98 86 3313 6055

Email

A.abolfathi123@gmail.com

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