Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of I LOV U massage on the gastric residual volume of patients under intestinal nutrition hospitalized in intensive care units of Ali Ibn Abi Taleb Hospital in Rafsanjan

Protocol summary

Study aim

Determining the effect of I LOV U massage on the amount of residual stomach volume in patients under enteral nutrition admitted to the special care units of Ali Bin Abitalib Rafsanjan Hospital.

Design

Clinical trial with control group, without blinding, randomized, on 80 patients. The random minimization method is used for randomization.

Settings and conduct

This research is carried out in the ICU department of Ali Bin Abitaleb Hospital in Rafsanjan. The participants are selected according to the available method and based on the entry criteria, and are placed in two intervention and control groups using the random minimization method. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Absence of oral feeding and having a nasogastric feeding tube 2- Glasgow coma scale less than 9 3- Absence of abdominal radiotherapy in the last 6 weeks 4- Not having a wound or recent surgery on the stomach or digestive system (10 days or less) 5- Age above 18 years Exclusion criteria: 1- Discharge or death of the patient before completing the intervention period 2- Patients with liver failure, abdominal aortic aneurysm and ascites 3- Making the patient vomit 4- Patient being NPO

Intervention groups

In the intervention group, abdominal massage using the I LOV U method is used. The massage course for the intervention group is performed twice a day for 20 minutes each time for three days. The interval between two massages is 2 hours. GRV will be measured and checked every day before the intervention (9 am) and 1 hour after the second massage (12 noon). There is no intervention in the control group.

Main outcome variables

The main outcome variable of the present study is the amount of remaining stomach volume.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231004059620N1**
Registration date: **2023-10-25, 1402/08/03**
Registration timing: **prospective**

Last update: **2023-10-25, 1402/08/03**
Update count: **0**

Registration date

2023-10-25, 1402/08/03

Registrant information

Name

Zakiesadat Mirahmadiniri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-14, 1402/08/23

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of I LOV U massage on the gastric residual volume of patients under intestinal nutrition hospitalized in intensive care units of Ali Ibn Abi Taleb Hospital in Rafsanjan

Public title

Investigating the effect of massage on the residual volume of the stomach

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Absence of oral feeding and having a nasogastric feeding tube Glasgow coma scale less than 9 Absence of abdominal radiotherapy in the last 6 weeks Not having a wound or recent surgery on the stomach or digestive system (10 days or less) Age above 18 years Absence of paralysis of the veins based on the diagnosis of the attending physician Not taking laxatives Absence of pregnancy Not taking prokinetic drugs such as metoclopramide and erythromycin within 8 hours before the intervention. More than 24 hours have passed since the patient was admitted to the ICU More than 24 hours have passed since the start of enteral nutrition Patients with received gavage volume of 100-300 cc based on ward routine

Exclusion criteria:

Discharge or death of the patient before completing the intervention period Patients with liver failure, abdominal aortic aneurysm and ascites Making the patient vomit Patient being NPO Average body mass ≥ 30

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The method used for randomizing participants into two groups, one for the intervention and the other as the control, is known as "random minimization." To implement this method, the researchers first organize participants into classes based on a measure called the Apache score. These classes help categorize participants with similar characteristics. Then, the first to fourth participants are randomly assigned to either the intervention or control group. However, there's a unique aspect to this method: rather than solely relying on random chance, the researchers look at the total scores of specific indicators within each group. The sample is assigned to the group with a lower total score. This approach aims to create more balanced groups with respect to the selected indicators. In simpler terms, random minimization starts by categorizing participants based on their Apache scores. Then, a combination of random selection and score comparison is used to assign participants to either the intervention or control group, ensuring that the groups are well-balanced with respect to these scores.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Rafsanjan University of Medical Sciences

Street address

Rafsanjan - Imam Ali Boulevard - Rafsanjan University of Medical Sciences - Central Organization - Building No. 3, Deputy for Research and Technology

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2022-12-07, 1401/09/16

Ethics committee reference number

IR.RUMS.REC.1401.176

Health conditions studied

1

Description of health condition studied

Patients admitted to the intensive care unit

ICD-10 code

E63

ICD-10 code description

Other nutritional deficiencies

Primary outcomes

1

Description

Gastric Residual Volume (GRV)

Timepoint

GRV is measured and checked every day before the intervention (9 am) and 1 hour after the second massage (12 noon).

Method of measurement

Standard 60 cc gavage syringe (manufactured by Hilal Medical Equipment Company with number 90077826837 available in the department)

Secondary outcomes

1

Description

Reducing the volume of the remaining stomach

Timepoint

GRV is measured and checked every day before the intervention (9 am) and 1 hour after the second massage (12 noon).

Method of measurement

Standard 60 cc gavage syringe (manufactured by Hilal Medical Equipment Company with number 90077826837 available in the department)

Intervention groups

1

Description

Intervention group: In the intervention group, abdominal massage using I LOV U method is used. The massage course for the intervention group will be performed twice a day for 20 minutes each time for three days. The interval between two massages is 2 hours. GRV is measured and checked every day before the intervention (9 am) and 1 hour after the second massage (12 noon). For female patients in the intervention group, abdominal massage is performed by the researcher himself and for male patients by the help of a male researcher under the supervision of the researcher in the bed where the patient is lying by placing a screen. Before the intervention, it is taught theoretically and practically with the help of a male researcher. I LOV U massage method: Circular massage is performed in a clockwise direction according to bowel movements on the abdominal wall with medium pressure. Abdominal massage circular movements in the form of the letters I, L, U, and O towards the movements of the large intestine and small intestine are performed as follows: for the left side massage, the patient is placed in a lying position on the back, and the massage is performed in a circular manner by writing The letter I is performed on the left upper quadrant (LUQ) and continues vertically downward along the left lower quadrant (LLQ) to the top. To write the letter L, massage starts from the right lower quadrant of the abdomen (RLQ) along the ascending part of the colon to the right upper quadrant (RUQ) and then from the transverse part of the colon massage to the left upper quadrant (LUQ). To write the letter O exactly around the navel, massage along the small intestine. To write the letter U, all the parts massaged by writing I and L are massaged continuously. To write the letter U, massage starts from the right lower quadrant (RLQ) along the ascending colon to the right upper quadrant (RUQ) and then continues along the transverse colon to the left upper quadrant (LUQ). Next, the left upper quadrant (LUQ) is massaged and continues vertically downward along the descending colon to the LLQ.

Category

Behavior

2

Description

Control group: no intervention is performed in the control group. In this group, only gavage is done based on the department's routine.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebn Abi Taleb Hospital

Full name of responsible person

Seyyed Mohammad Ibrahim

Street address

Rafsanjan, Ali Ibn Abi Talib (A.S.) Square, Hazrat Ali Ibn Abi Talib (A.S.) Educational and Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Rafsanjan 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
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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 is potentially shareable after de-identifying individuals
When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions, or people who are also engaged in industry can apply to receive them.

Under which criteria data/document could be used

These documents can be used and accessed only for further investigation and clarification of the working method used in the present study.

From where data/document is obtainable

Ali KHodadadizadeh, faculty of Rafsanjan University of Medical Sciences email: akhodadadi67@gmail.com

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

Send an email to the person responsible for this project with details and logical reasons. Then, in case of discretion and approval, the data will be sent after 10 working days.

Comments