Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of abdominal massage on gastrointestinal function and aspiration incidence among patients hospitalized in intensive care units in Shahid Bahonar hospital of Kerman University of Medical Sciences in 2017

Protocol summary

Summary

Introduction:Enteral feedimg through nasogastric tube is common in ICU patients, but there is some complications. These complications can be effected enough protein and energy need in ICU patients. As a result, these patients do not reach the targeted calorie. Malnutrition has been reported about 35% in ICU patients. as a result Prolong the time of mechanical ventilation and hospitalization in ICU. Studies have shown that abdominal massage may reduce complications and improve digestive function and can be increased the rate of gastric emptying in patients with high gastric residual volume. Objective: To evaluate the effect of abdominal massage on gastrointestinal function in patients with endotracheal tube in intensive care units. Design: This is a randomized clinical trail. Setting and Conduct: After getting ethical code and coordination with intensive care units, researcher will start the study. convenience sampling will use to collect the eligible subjects then they will allocated to intervention or control group by randomization (using minimization). The subjects will be assess for three days. Participants: In this study, population consisted of patients admitted to the intensive care unit who has an artificial airway and enterally fed intermittently via nasogastric tube. The study will conduct with 70 subjects, 35 in the massage group and 35 in the control group. Inclusion criteria: included subjects who were being fed intermittently and enterally via a nasogastric tube; age over 18 years; no receive prokinetic of medications such as metoclopramide and anticholinergics agents such as atropine; consciousness (GCS) less than 9; no receive radiotherapy and abdominal surgery in the previous 6 weeks; and absence of contraindication to abdominal massage. Exclusion criteria included: subjects who having vomiting; NPO for doing laboratory tests and surgical procedures; incidence diarrhea; discharge from ICU or death less than 3 days; Hyper glycaemia and hypokalemia; , GII bleeding; patientes be extubated before 3 days; patients who have aspiration Before entering the study; patientes because of severe trauma have is not been able to get on the suitable position for massage; patientes have spinal cord injury; ascites during the study. Intervention: Abdominal massage is only applied to the massage group. subjects in massage group receive 15 minutes abdominal massage, 2 times daily for 3 consecutive days, 30 minutes before feeding at 8:30 a.m., and 8:30 p.m. During massage application, the subject is placed in a supine position with the head-of-bed elevated at 30°–45°. The abdominal massage is applied in a clockwise direction over the abdominal wall, based on four basic strokes are typically used in Swedish massage: stroking, effleurage, kneading, and vibration. Main outcome: Distention, gastric residual volume, defecation frequency, constipation and aspiration will be checked before and after the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030531972N2**
Registration date: **2017-06-20, 1396/03/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-20, 1396/03/30

Registrant information

Name

Mahlagha Dehghan Anari

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Recruitment status
Recruitment complete
Funding source
Vice Chancellor for Research of Kerman University of Medical Sciences

Expected recruitment start date
2017-04-20, 1396/01/31
Expected recruitment end date
2017-09-30, 1396/07/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of abdominal massage on gastrointestinal function and aspiration incidence among patients hospitalized in intensive care units in Shahid Bahonar hospital of Kerman University of Medical Sciences in 2017

Public title
The effect of abdominal massage on gastrointestinal function
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:Over age 18 years up to 70ears; nutrition by nose-feed tube to enteral feeding alternative methods; have not received metoclopramide, erythromycin, cisapride, and anticholinergic agents; have not received radiotherapy treatment and surgery on the abdominal region in the previous 6 weeks; have no contraindication to abdominal massage for examples: cellulitis, abdominal mass, peritonitis, abdominal aneurysm, ascites (Recognizing doctor), consciousness (GCS) less than 9. Exclusion criteria: having vomiting (view the contents reflux regardless of its value) (vomiting increase the risk of aspiration effect); NPO for doing laboratory tests and surgical procedures; incidence diarrhea (having 3 or more loose stools per day times the volume More200-250 cc); discharge from ICU or death less than 3 days; hyperglycemia (blood sugar more than 200) and hypokalemia (potassium level less than3/5); GI bleeding (Recognizing doctor); patientes be extubated before 3 day; patients who have aspiration Before entering the study; patientes because of severe trauma have is not been able to get on the suitable position for massage; patientes have spinal cord injury; incidence ascites during the study.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Ethics committee of Kerman University of Medical Sciences
Street address
Ebnesina St،Jahad Blvd، Somaye Crossroad، Kerman
City
kerman
Postal code
Approval date
2017-02-19, 1395/12/01
Ethics committee reference number
IR.KMU.REC. 1395.891

Health conditions studied

1

Description of health condition studied
coma
ICD-10 code
R40.2
ICD-10 code description
Coma،Unspecified

2

Description of health condition studied
Brain tumor
ICD-10 code
D33
ICD-10 code description
Benign neoplasm of brain and other parts of central

nervous system

3

Description of health condition studied
Head trauma
ICD-10 code
F07.2
ICD-10 code description
Post- concussional syndrome

4

Description of health condition studied
Malignant Brain tumor
ICD-10 code
C71
ICD-10 code description
Malignant neoplasm of brain

5

Description of health condition studied
Acute respiratory failure
ICD-10 code
J96.0
ICD-10 code description
Respiratory failure, not elsewhere classified

Primary outcomes

1

Description
constipation
Timepoint
end three day
Method of measurement
not defecation during three day

2

Description
distention
Timepoint
first day and last day
Method of measurement
by measurement circumference abdoman

3

Description
defecation
Timepoint
daily
Method of measurement
number defecation

4

Description
Gastric residual volume
Timepoint
before every feeding
Method of measurement
with 50 cc feeding syring

5

Description
aspiration
Timepoint
end three day
Method of measurement
determination airway secretion PH and glucose

Secondary outcomes

empty

Intervention groups

1

Description
Abdominal massage 15 minutes before nasogastric tube feeding on interventional group
Category
Other

2

Description
No intervention in control group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
ICU departments, Shahid Bahonar Hospital
Full name of responsible person
Mahlagha Dehghan
Street address
Baghemelli sq، Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Kerman University of Medical Sciences
Full name of responsible person
Dr. Mehdi Ansari
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Ebnesina St،Jahad Blvd، Somaye Crossroad، Kerman
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kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty