Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of abdominal massage on feeding tolerance via intermittent nasogastric feeding tube in critically ill patients.

Protocol summary

Summary

Objective: 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. Studies have shown that abdominal massage can be increased the rate of gastric emptying in patients with high gastric residual volume. In this randomized clinical trial study, population consisted of patients admitted to the intensive care unit and enterally fed intermittently via nasogastric tube. The study was conducted with 80 subjects, 40 in the massage group and 40 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 metoclopramide, erythromycin, cisapride, and anticholinergic agents, no receive radiotherapy and abdominal surgery in the previous 6 weeks, and absence of contraindication to abdominal massage. In the data collection stage, if two times consecutively vomiting or diarrhea was observed in subjects in the massage group, is excluded from the study. In both control and massage group gastric residual volume has being measured by aspirating with 50 ml syringe before each feeding. Subjects is fed through a nasogastric tube 7 meals in a day, from 6 a.m. untill 12 midnight, in the 30-45 head up position and by gravity via gavage syringe. Abdominal massage is only applied to the massage group subjects for 10 minutes, 3 times daily for 3 consecutive days,30 minutes before feeding at 8:30 a.m., 2:30 p.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. The accepted criteria for food tolerance include a GRV less than half of the food amount given in the previous meal and absence of vomiting and diarrhea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090618815N1**
Registration date: **2015-12-28, 1394/10/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-12-28, 1394/10/07

Registrant information

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Roya Haddadi
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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2014-10-07, 1393/07/15

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of abdominal massage on feeding tolerance via intermittent nasogastric feeding tube in critically ill patients.

Public title
The effect of abdominal massage on feeding tolerance
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Subjects who were being fed intermittently enterally via a nasogastric tube; Over age 18 years up to 70 years; Recently started on intermittent enteral feeding, maximum after giving 3 feed; 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, diverticulitis, probability of thromboembolic events in recent one year, positive history and probability of DVT in one recent year. Exclusion criteria: Have two times consecutively vomiting(less than 12 hours); Develop diarrhea more than 3 times a day; Receive metoclopramide for vomiting; Discharge patients from ICU or death less than 3 days; Make patients NPO more than 12 hours for procedures or laboratory tests.
Age
From **18 years** old to **70 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
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 Tehran University of Medical Sciences
Street address
Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2013-06-22, 1392/04/01
Ethics committee reference number
91/130/3546/د

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
Head trauma
ICD-10 code
F07.2
ICD-10 code description
Post- concussional syndrome

3

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

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
Alzheimer
ICD-10 code
G30
ICD-10 code description

Alzheimer disease

Primary outcomes

1

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

2

Description
Diarrhea
Timepoint
Every shift
Method of measurement
Frequency

3

Description
Vomiting
Timepoint
Every shift
Method of measurement
Frequency

Secondary outcomes

empty

Intervention groups

1

Description
Abdominal massage 30 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
Valiasr Hospital
Full name of responsible person
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Tehran University of Medical Sciences
Full name of responsible person
Dr.Masoud Yonesian
Street address
Central Organization of Tehran University of Medical Sciences, Keshavarz Blvd.
City
Tehran
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 Tehran 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

Person responsible for general inquiries

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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