

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

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

Protocol summary

Summary

Objective: Enteral feeding 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

Name

Roya Haddadi

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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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

91/130/3546/3

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

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

2

Recruitment center

Name of recruitment center

Imam khomeini Hospital

Full name of responsible person

Street address

City

Tehran

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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

M.s of Critical Care Nursing

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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