

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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 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. 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; , GI 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

**Name of organization / entity**

Kerman University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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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 70 years; 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 More 200-250 cc); discharge from ICU or death less than 3 days; hyperglycemia (blood sugar more than 200) and hypokalemia (potassium level less than 3/5); GI bleeding (Recognizing doctor); patients be extubated before 3 day; patients who have aspiration Before entering the study; patients because of severe trauma have is not been able to get on the suitable position for massage; patients 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**

Ebnesima 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 abdomen

### 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 syringe

### 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

##### **City**

Kerman

## **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

##### **Street address**

Ebnesima St, Jahad Blvd, Somaye Crossroad, Kerman

##### **City**

kerman

**Grant name**

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**Grant code / Reference number**

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**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*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Fatehipoor Amanallah

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**Web page address****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*