

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Dec 2019

The effect of abdominal massage on gastric residual volume and abdominal circumference of patients a

Protocol summary

Summary

This study is performed as a randomized, double blind clinical trial. The study population included patients admitted to intensive care units in two hospitals of Golestan and Imam Khomeini in Ahvaz. Eligible patients are randomly selected and randomly assigned to test and control groups. According to the studies, there are two types of abdominal massage, Classic abdominal massage and massage based on the tensegrity principle. The present study uses massage based on the tensegrity principle. This massage technique consists of 5 steps. The massage starts with brushing the skin in the abdominal area, second stage elastic deformation of the thoracolumbar fascia will be performed in the form of displacement, third stage The abdominal integuments is elastically deformed by kneading, The fourth stage involves shock movements along the armpit from top to bottom and down to the top and The last stage contains Elastic deformation of the muscles in the intercostal spaces. The patient's position is asleep to the back while undergoing massage. The angle between the bed and the patient's head is 30 to 45 degrees, and the patient's legs are placed on a pillow. This condition helps to relax the abdominal muscles. Massage is runs twice for each patient, Massage session lasts about 20 minutes. This action runs over 3 consecutive days. There is no intervention for the control group. every day, before and after the massage, gastric residual valuum and abdominal circumference Calculated and Compare.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062134641N2**
 Registration date: **2017-07-26, 1396/05/04**
 Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-26, 1396/05/04

Registrant information

Name

Alireza Abdi

Name of organization / entity

nursing and midwifery school, Kermanshah university of medical sciences

Country

Iran (Islamic Republic of)

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+98 83 3725 0111

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2017-11-11, 1396/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of abdominal massage on gastric residual volume and abdominal circumference of patients a

Public title

The effect of abdominal massage on the gastric residual valume

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having a nasogastric tube, Loss of consciousness, had not received radiotherapy treatment on the abdominal region in the previous 6 weeks, without intestinal obstruction, abdominal surgery, or diarrhea, Lack of Deep Venus Thrombosis, Not having an aneurysm, Not having ascites, Not receiving any effective gastrointestinal medicine Exclusion criteria: Transferring the patient to other wards, death, discharge,

Take out the gastric tube, Patients have intra-abdominal pressure 12 mm Hg and patients with abdominal compartment syndrome

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

None

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Kermanshah University of Medical Sciences

Street address

Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blv.

City

Kermanshah

Postal code

6714634698

Approval date

2017-05-03, 1396/02/13

Ethics committee reference number

Kums.rec.1396.31

Health conditions studied**1****Description of health condition studied**

Acute pulmonary edema

ICD-10 code

150.1

ICD-10 code description

Left ventricular failure

2**Description of health condition studied**

head trauma

ICD-10 code

s06.7

ICD-10 code description

Intracranial injury with prolonged coma

3**Description of health condition studied**

Congestive heart failure

ICD-10 code

150.0

ICD-10 code description

Congestive heart failure

Primary outcomes**1****Description**

gastric residual volume

Timepoint

before and after intervention

Method of measurement

Using a special syringe for gavage

2**Description**

abdominal circumference

Timepoint

before and after intervention

Method of measurement

Using a special flexible meter

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: According to the studies, there are two types of abdominal massage, Classic abdominal massage and massage based on the tensegrity principle. The present study uses massage based on the tensegrity principle. This massage technique consists of 5 steps. The massage started with brushing the skin in the abdominal area, second stage elastic deformation of the thoracolumbar fascia was performed in the form of displacement, third stage The abdominal integuments were elastically deformed by kneading, The fourth stage involves shock movements along the armpit from top to bottom and down to the top and The last stage contains Elastic deformation of the muscles in the intercostal spaces. The patient's position is asleep to the back while undergoing massage. The angle between the bed and the patient's head is 30 to 45 degrees, and the patient's

legs are placed on a pillow. This condition helps to relax the abdominal muscles. Massage is runs twice for each patient, Massage session lasts about 20 minutes in each day. This action runs over 3 consecutive days. every day, before and after the massage, gastric residual valuum and abdominal circumference Calculated and Compare. For abdominal circumference measurement, a 150-cm flexible measure will be used. The beginning point for the measurement is the umbilicus.

Category

Prevention

2

Description

Control group: The control group will receive usual care contain; Change position, Lavage, Gavage and etc.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

alireza abdi

Street address

ahvaz-Golestan region- farvardin street

City

ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kermanshah University of Medical Sciences

Full name of responsible person

behrooz hamzeh

Street address

Shahid Beheshty BLV., Kermanshah University of Medical Sciences, Kermanshah

City

kermanshah

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, Kermanshah 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

Kermanshah School of Nursing and Midwifery

Full name of responsible person

alireza abdi

Position

PhD in Nursing Education-Faculty member

Other areas of specialty/work

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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*