

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of gastric gases discharge on enteral feeding tolerance and function of the gastrointestinal system in patients undergoing mechanical ventilation with nasogastric feeding tube.

Protocol summary

Summary

The aim of this study was to determine effect of gastric gases discharge on enteral feeding tolerance in patients undergoing mechanical ventilation with nasogastric feeding tube. Inclusion criteria: traumatic patients under mechanical ventilation with CPAP; nutrition with solution prepared in the hospital. Exclusion criteria: Discharge or death of patient; stop gavage because of illness; conditions of semi-upright position is prohibited. In this study 60 patients aged 18 - 60 years old who are admitted in emdadi hospital with GCS less than or equal to 9 under mechanical ventilation with an endotracheal tube and fashion CPAP, will be randomly assigned into intervention or control group. In the intervention group nasogastric tube connected to a syringe without a plunger kept open 40 cm overhead 30 minutes after gavage, three times with an interval equal to one hour. And with hand is pressed as light about 2 cm in epigastric area. The patients in the control group do not receive any intervention. Gastric residual volume, abdominal distension, vomiting and diarrhea will be controlled before and after the test in both groups. At the end the results will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072223291N1**
Registration date: **2015-11-12, 1394/08/21**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-12, 1394/08/21

Registrant information

Name

Hossein Soltani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of gastric gases discharge on enteral feeding tolerance and function of the gastrointestinal system in patients undergoing mechanical ventilation with nasogastric feeding tube.

Public title

The effect of gastric gases discharge on enteral feeding tolerance

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patient satisfaction for the study; Age between 18-75 years old; traumatic patients under mechanical ventilation with CPAP; having a nasogastric tube No.14 - 16 ; nutrition with solution prepared in the hospital; have been passed more than 5 days from starting feeding through a nasogastric tube; No history of gastrointestinal surgery or the risk of disorders such as pancreatitis, gastrointestinal ulcers and lesions, gastrointestinal bleeding and gastrointestinal malignancies, liver and kidney failure, sores and infections in the abdomen; The patient not pregnant; No stretch limbs and head, pneumocephalus, diaphragm rupture, hemothorax and tension pneumothorax, chest floating, neck and spine injuries; lack of increased intracranial pressure; having GCS less than or equal 9. Exclusion criteria: Discharge or death of patient; stop gavage because of illness; conditions of semi-upright position is prohibited.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences

City

Gonabad

Postal code**Approval date**

2015-06-24, 1394/04/03

Ethics committee reference number

ir.gmu.rec.1394.27

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

Enteral Feeding Tolerance

ICD-10 code

E63.1

ICD-10 code description

Imbalance of constituents of food intake

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

Gastric Residual Volume

Timepoint

Every 3 hrs exactly before doing gavage

Method of measurement

By using 60cc gavage syringe

2**Description**

Gastric Distension

Timepoint

Every 3 hrs exactly before doing gavage

Method of measurement

Physical Examination

3**Description**

Vomiting

Timepoint

Every 3 hrs exactly before doing gavage

Method of measurement

Observation

4**Description**

Diarrhea

Timepoint

24 hrs before and after intervention

Method of measurement

Observation

Secondary outcomes**1****Description**

Arterial Oxygen Saturation

Timepoint

Every 3 hrs exactly before doing gavage

Method of measurement

By pulse oximetry

2

Description

Tidal Volume

Timepoint

Every 3 hrs exactly before doing gavage

Method of measurement

Ventilator Machine

Intervention groups

1

Description

In the intervention group: Nasogastric tube connected to a syringe without a plunger kept open 40 cm overhead 30 minutes after gavage, three times with an interval equal to one hour. And with hand is pressed as light about 2 cm in epigastric area. The patients in the control group do not receive any intervention. Gastric residual volume, abdominal distension, vomiting and diarrhea will be controlled before and after the test in both groups. This intervention is done twice a day.

Category

Prevention

2

Description

Control group: Without action

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emdadi Hospital

Full name of responsible person

Hossein Soltani

Street address

Emdadi Hospital, Fadaein Eslam Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Javad Keramaty

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City

Gonabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Hossein Soltani

Position

Master degree student in critical care nursing

Other areas of specialty/work

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Person responsible for scientific 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