Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 gavagbecause of illness; conditions of semi-upright position is prohibited. in this study 60 patients aged 18 - 60 years old.who are admitted in emdadi haspital 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 intevetion 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 contorol group do not receive any intervention. Gastric residual volume, abdominal distension, vomiting and diarrhea will be controled 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

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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, hemeuthorax 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 gavagbecause 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 gavag

Method of measurement
By using 60cc gavage syrige

2

Description
Gastric Distension

Timepoint
Every 3 hrs exactly before doing gavag

Method of measurement
Physical Examination

3

Description
Vometing

Timepoint
Every 3 hrs exactly before doing gavag

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 gavag
Method of measurement
Ventilator Machine

Intervention groups

1

Description
In the intevetion 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 contorol group do not receive any intervention. Gastric residual volume, abdominal distension, vomiting and diarrhea will be controled before and after the test in both groups. This intervention is done twice a day.
Category
Prevention

2

Description
Cotrol group: Without action
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emdadi Haspital
Full name of responsible person
Hossein Soltani
Street address
Emdadi Haspital, Fadaein Eslam Street
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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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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
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Master degree student in 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