Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Comparision of The Effect of Enteral Feeding ThroughThe Bolus & Continuous Methods on Paraclinical Outcome & Incidence of Diarrhea in Patient With Mechanical Ventilation

Protocol summary

Study aim

Effect of bolus and continuous enteral feeding on laboratory parameters and incidence of diarrhea in patients with mechanical ventilation

Design

The clinical trial has a control group, with parallel groups, single blind, randomized, phase 3 trial with a sample size of 34 patients.

Settings and conduct

Patients admitted to the intensive care unit of imam Khomeini hospital of Tehran who were eligible for inclusion in the study were divided into two study groups.in the intervention group, the patient started feeding at 25 cc / h and in the control group at 75cc / 3h.On the first day of gavage, we reached 50% of the patient's nutritional goal and within 48 hours we reached the final goal of feeding the patients at 25kcal / kg / day.the incidence of diarrhea during one week was recorded in both groups. At the end of one week of intervention, albumin, phosphate and lactate were measured and pre-albumin was measured 48 hours after intervention. Glucose index was also checked and recorded every 6 hours during the intervention.blinding was performed unilaterally (participants).

Participants/Inclusion and exclusion criteria

Inclusion criteria:-The patient's intubation through the tracheal tube- Feeding the patient through the gastric tube- Patient companions' consent to participate in the study- Ages 18-85- Body mass index between 18-30Exclusion criteria:- Having diarrhea at the beginning of the study- Having bowel and ileus obstruction- Being diagnosed with kidney failure- Having an ileostomy and a colostomy

Intervention groups

Intervention group: continuous enteral feeding Control group: bolus enteral feeding

Main outcome variables

Determination and Comparison of Albumin, Phosphate, Pre-Albumin, Lactate and Blood Glucose Levels in Patients Under Mechanical Ventilation in the Bolus and Continuous Nutrition Group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042528N1**
Registration date: **2020-01-18, 1398/10/28**
Registration timing: **retrospective**

Last update: **2020-01-18, 1398/10/28**
Update count: **0**

Registration date

2020-01-18, 1398/10/28

Registrant information

Name

Javad Seyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3632 4105

Email address

jseyedi30@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-06, 1397/07/14

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

2018-10-06, 1397/07/14

Actual recruitment end date

2019-09-11, 1398/06/20

Trial completion date

2019-09-21, 1398/06/30

Scientific title

Comparision of The Effect of Enteral Feeding ThroughThe Bolus & Continuous Methods on Paraclinical Outcome & Incidence of Diarrhea in Patient With Mechanical Ventilation

Public title

Effect of Enteral Feeding on Paraclinical Outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with mechanical ventilation throught the endotracheal tube Feeding of Patient with NG tube Patient attendant satisfaction 18-85 years old

Exclusion criteria:

Patient with digestive Disease(diarrhea, ileus, obstruction, ostomy) Patient with renal failure

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Study participants are randomly assigned to study groups

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 scinces

Street address

No.1,Langroudi Ave.,Imam Khomeyni Blvd

City

Tehran

Province

Tehran

Postal code

1319847858

Approval date

2018-09-02, 1397/06/11

Ethics committee reference number

IR.TUMS.FNM.REC.1397.103

Health conditions studied

1

Description of health condition studied

Paraclinical changes in continuous feeding and bolus feeding

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum albumin level

Timepoint

Before the intervention and 7 days after the intervention

Method of measurement

Analysis by Bromocresol Green Pars Test Laboratory Kit

2

Description

Serum level of pre-albumin

Timepoint

Before the intervention and 2 days after the intervention

Method of measurement

Analysis by Nephlometry Laboratory Kit Brand Binding site

3

Description

Serum phosphate level

Timepoint

Before the intervention and 7 days after the intervention

Method of measurement

Photometric analysis uv test

4

Description

Serum lactate level

Timepoint

Before the intervention and 7 days after the intervention

Method of measurement

Enzymatic / colorimetric analysis kit by Fars Bayer Lab

5

Description
Frequency of defecation
Timepoint
During 7 days of intervention
Method of measurement
View and record in data log sheet

6

Description
Patient's blood sugar
Timepoint
Every six hours
Method of measurement
clever check Glucometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Patients in this group received continuous enteral feeding with standard commercial solution of enterameal of karen group. After adding 11.3 g of powder to 50 cc of water, each cc contains one kcal of energy. In this method, the patient started feeding at 25cc / h in a semi-seated position. And every three hours the volume of gastric residue was measured, and if the volume of gastric residue was less than 50% of the volume of the patient's previous three hours, the patient's gavage was continued and the patient's gavage volume was increased in calories, if any. When the volume of the stomach was more than 50% of the volume of gavage in the last three hours, the patient's gavage was cut for three hours. On the first day of the patient's gavage, 50% of the patient's nutritional intake was met, and within 48 hours we reached the final nutritional goal of 25kcal / kg / day, and continued with the same target volume until the end of the study ...
Category
Treatment - Other

2

Description
Control group: Patients in this group received enteral feeding through routine (bolus) and with standard commercial enterameal solution. After adding 11.3 g of powder to 50 cc of water, each cc contains one kcal of energy. In this method, the patient started feeding at a rate of 75cc / 3h in a semi-sitting position And every three hours the volume of gastric residue was measured, and if the volume of gastric residue was less than 50% of the volume of the patient's previous three hours, the patient's gavage was continued and the patient's gavage volume was increased in calories, if any. When the volume of the stomach was more than 50% of the volume of gavage in the last three hours, the patient's gavage was cut for three hours. On the first day of the patient's gavage, 50% of the patient's nutritional intake was met, and within 48 hours we reached the final nutritional goal of 25kcal / kg / day, and continued with the same target volume until the end of the study ...
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Javad Seyyedi
Street address
No.1,Langhroudi Al., Imam Khomeini Ave.,
City
Tehran
Province
Tehran
Postal code
1319847858
Phone
+98 21 6638 7619
Email
jseyedi30@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohamad Ali Sahraian
Street address
Qods Ave., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
-
Phone
+98 21 8163 3686
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source

100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Javad Seyyedi

Position
Master of Scince Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only original data is shared

When the data will become available and for how long
1 year after publishing the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Comparison with data from similar studies

From where data/document is obtainable
jseyedi30@yahoo.com

What processes are involved for a request to access data/document
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Comments