

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### Comparison of The Effect of Enteral Feeding Through The 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 18-30  
Exclusion 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 Nephelometry 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 Science Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Contact**

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**Person responsible for updating data**

**Contact**

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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**