

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jul 2026

### The effect of planned feeding on the duration of patient separation from mechanical ventilation and stay in the intensive care unit

#### Protocol summary

##### Study aim

Determining the effect of planned feeding on the duration of patient separation from mechanical ventilation and length of stay in the intensive care unit

##### Design

This study is a clinical trial with a control, parallel, Non-random groups on 42 patients with inclusion criteria by available sampling method.

##### Settings and conduct

The population studied in this study consists of patients admitted to the intensive care units of Imam and Golestan hospitals in Ahvaz that are in accordance with the inclusion and exclusion criteria of this study and the intervention in the intervention group will include nutrition based on the patient's needs.

##### Participants/Inclusion and exclusion criteria

1. Hospitalized in the intensive care unit up to 24 hours after admission to the hospital 2. Age 18 to 65 years 3. Feeding through nasopharyngeal catheter 4. Patients under mechanical ventilation for more than 24 hours 5. No pregnancy 6. Lack of obesity 7. Patient with Liver and kidney disease or severe infection

##### Intervention groups

Control: supplying energy from a handmade hospital solution without interfering with its preparation  
Intervention: Energy supply from standard Entera-Meal solution.

##### Main outcome variables

1. Serum pre-albumin level in the intervention and control groups 2. Duration of patient connection to ventilator in both groups 3. The length of stay in intensive care unit in both groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200813048398N1**

Registration date: **2020-08-22, 1399/06/01**

Registration timing: **prospective**

Last update: **2020-08-22, 1399/06/01**

Update count: **0**

##### Registration date

2020-08-22, 1399/06/01

##### Registrant information

###### Name

Sakineh Javdan

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences and Health Services, Vice Chancellor for Research a

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3333 2368

###### Email address

javdansakineh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-09, 1399/06/19

##### Expected recruitment end date

2020-12-09, 1399/09/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of planned feeding on the duration of patient separation from mechanical ventilation and stay in the intensive care unit

**Public title**

The effect of feeding on the duration of patient separation from mechanical ventilation

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria****Inclusion criteria:**

Hospitalized in the intensive care unit up to 24 hours after admission to the hospital Age 18 to 65 years Feeding through nasopharyngeal catheter Patients under mechanical ventilation for more than 24 hours No pregnancy Lack of obesity (patients with a body mass index above 40) Patient with Liver disease or severe infection Patient with kidney disease

**Exclusion criteria:**

Change the type of feeding from gavage to complete intravenous feeding Transfer or discharge the patient from the ICU

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Not randomized

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

Not 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 Ahvaz Jundishapur University of Medical Sciences

**Street address**

Vice Chancellor for Research and Technology Development, next to the central organization of Ahvaz Jundishapur University of Medical Sciences and Health Services, university city, Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

15794 61357

**Approval date**

2020-05-15, 1399/02/26

**Ethics committee reference number**

IR.AJUMS.REC.1399.190

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

The effect of planned feeding on the duration of patient isolation from mechanical ventilation and the length of stay in the intensive care unit

**ICD-10 code**

R63.3

**ICD-10 code description**

Feeding difficulties

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

Serum pre-albumin level in the intervention and control groups

**Timepoint**

Before and after the intervention

**Method of measurement**

Laboratory

**2****Description**

Duration of patient connection to ventilator in two groups of intervention and control

**Timepoint**

Before and after the intervention

**Method of measurement**

chronometer

**3****Description**

The length of stay in intensive care unit between intervention and control groups

**Timepoint**

Before and after the intervention

**Method of measurement**

Number of days the patient is hospitalized

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

Serum prealbumin levels in both intervention and control groups

**Timepoint**

Before and after the intervention

**Method of measurement**

Laboratory

## 2

### **Description**

Duration of patient connection to ventilator in two groups of intervention and control

### **Timepoint**

Before and after the intervention

### **Method of measurement**

chronometer

## 3

### **Description**

The length of stay in intensive care unit between intervention and control groups

### **Timepoint**

Before and after the intervention

### **Method of measurement**

Number of days the patient is hospitalized

## **Intervention groups**

## 1

### **Description**

Intervention group: In the intervention group to supply energy the standard EnteraMeal solution will be used which has one kilocalorie of energy per milliliter and the distribution of macronutrients as 14% energy from protein, 33% energy from fat and 54% energy from carbohydrates. To prepare 150 ml, 33 g (one measure) of EnteraMeal powder is poured into 120 ml of cooled boiled water and this solution has one kilocalorie per ml of energy. Feeding is performed by Intragastric nasogastric tube by bolus infusion method with a 60 cc syringe which to reach the calculated energy in 48-72 hours Start with 50 cc and add 30 cc every three hours. The schedule of prescribing hours is as follows: 6, 9, 12, 15, 18 and 21.

### **Category**

Diagnosis

## 2

### **Description**

Control group: In the control group, hospital gavage fluid will be used without interfering in it's preparation method Which is sent to the Laboratory of Nutrition Department of Paramedical School for analysis of macronutrients and energy.

### **Category**

Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Ahvaz Imam Khomeini Hospital

#### **Full name of responsible person**

Marzieh Asadizaker

#### **Street address**

Azadegan Ave. - Imam Khomeini Medical Center of Ahvaz

#### **City**

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#### **Province**

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#### **Phone**

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#### **Email**

javdansakineh@gmail.com

## 2

### **Recruitment center**

#### **Name of recruitment center**

Ahvaz Golestan Hospital

#### **Full name of responsible person**

Marzieh Asadizaker

#### **Street address**

Golestan Educational and Medical Center, Farvardin Ave

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## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Ahvaz University of Medical Sciences

#### **Full name of responsible person**

Mohammad Badvi

#### **Street address**

Ahvaz Jundishapur University of Medical Sciences and Health Services, Golestan Ave, Ahvaz, Khuzestan Province

#### **City**

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#### **Email**

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### **Grant name**

### **Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Sakineh Javdan

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**Ahvaz Jundishapur University of Medical Sciences and  
Health Services, Golestan Ave, Ahvaz, Khuzestan  
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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Marzieh Asadzaker

**Position**

Associate professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no need to mention them in the trial.

**Study Protocol**Undecided - It is not yet known if there will be a plan to  
make this available**Statistical Analysis Plan**Undecided - It is not yet known if there will be a plan to  
make this available**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**Undecided - It is not yet known if there will be a plan to  
make this available**Analytic Code**Undecided - It is not yet known if there will be a plan to  
make this available**Data Dictionary**Undecided - It is not yet known if there will be a plan to  
make this available