

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 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)

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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

Khuzestan

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 Intra-gastric 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 its 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 Asadzaker

Street address

Azadegan Ave. - Imam Khomeini Medical Center of Ahvaz

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Recruitment center

Name of recruitment center

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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

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

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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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