Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 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

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Sakineh Javdan

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences and Health Services, Vice Chancellor for Research a

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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
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
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2

Recruitment center
Name of recruitment center
Ahvaz Golestan Hospital
Full name of responsible person
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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
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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
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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