Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment the effect of enteral feeding riched with wheat germ on weaning from mechanical ventilatory of patients admitted to intensive care unit of Urmia Imam Khomeini Hospital

Protocol summary

Study aim

To determine the effect of enteral feeding enriched with wheat germ on weaning from mechanically ventilated of patients admitted to the intensive care unit

Design

Single-blind, Randomized clinical trial

Settings and conduct

100 patients undergoing mechanical ventilation in the intensive care unit of Urmia Imam Khomeini Hospital will be randomly assigned to the intervention or control group. enteral feeding for both groups will begin in the first 24 hours of admission. Additionally, patients in the intervention group will receive the 40% fat, 45% carbohydrate, 15% protein, and enriched with 100 grams of wheat germ. the control group will receive the Blenderized with 30% fat, 50% carbohydrate and 20% protein. The variables of study will be measured at baseline and weekly in both groups. The duration of the intervention will be from the first day of admission until weaning from the ventilator mechanical.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mechanically ventilated patients admitted to the intensive care unit; age 65-18 years, patients with a minimum length of stay 7 days. Exclusion criteria: Patients with Parenteral Feeding; Having chronic and acute renal failure; patients under Hemodialysis or peritoneal dialysis.

Intervention groups

The intervention group will receive the Blenderized of 40% fat, 45% carbohydrate, 15% protein and enriched with 100 grams of wheat germ. the control group will receive 30% fat, 50% carbohydrates, and 20% protein.

Main outcome variables

Duration of mechanical ventilation; duration of hospitalization in ICU; mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171221037983N3**
Registration date: **2018-05-16, 1397/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-16, 1397/02/26**
Update count: **0**

Registration date

2018-05-16, 1397/02/26

Registrant information

Name
Mohammad Amin Valizadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3346 9935
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valizademohammadamin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment the effect of enteral feeding riched with wheat germ on weaning from mechanical ventilatory of patients admitted to intensive care unit of Urmia Imam Khomeini Hospital

Public title
The effect of enteral feeding on weaning of mechanical ventilation patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients under mechanical ventilation in intensive care units age 18-65 years Patients with a minimum length of stay 7 days
Exclusion criteria:
Patients with Par-enteral Feeding Patients with chronic and acute renal failure Patients under hemodialysis or peritoneal dialysis
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients randomly will divide into two intervention or control groups. using random numbers table, a number will select as randomly. Patients will be assigned to the intervention or control groups according to the last number of medical records. The pair and Odd numbers will enroll in the intervention and control group, respectively.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients will be unaware of assign in the intervention or control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Imam Khimeini Hospital; Ershad Street; Modarres Blvd; Urmia; Iran
City
Urmia
Province
West Azarbaijan
Postal code
57157-89397
Approval date
2017-06-07, 1396/03/17
Ethics committee reference number
ir.umsu.rec.1396.88

Health conditions studied

1

Description of health condition studied
Patients under mechanical ventilation
ICD-10 code
T85.0
ICD-10 code description
Mechanical complication of ventricular intracranial (communicating) shunt

Primary outcomes

1

Description
Duration of mechanical ventilation
Timepoint
Admission to weaning from mechanical ventilation
Method of measurement
Duration of mechanical ventilation days

2

Description
Duration of admitted in ICU
Timepoint
From admission to discharge
Method of measurement
Duration of admitted in ICU days

3

Description
Mortality
Timepoint
From admission to mortality in ICU
Method of measurement
Patient's death

Secondary outcomes

1

Description

Body composition
Timepoint
Before and after intervention
Method of measurement
Body Analyzer In body S10

2

Description
Biochemistry tests include protein, albumin, sodium, magnesium, calcium
Timepoint
before and after intervention
Method of measurement
by kits

Intervention groups

1

Description
Intervention group: Blenderized of a combination of 40% fat, 45% carbohydrate, 15% protein and enriched with 100 grams of wheat germ
Category
Treatment - Other

2

Description
Control group: Blenderized of 30% fat, 50% carbohydrate and 20% protein.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Imam Khomeini Hospital
Full name of responsible person
Dr. Mohammad Amin Valizade Hasanlouei
Street address
Imam Khomeini Hospital; Ershad Street; Modarres Blvd; Urmia; Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Urmia University of Medical Sciences; Jahad street; Resalat Blvd; Urmia; Iran
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Postal code
57147-83734
Phone
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Email
mohebbi.i@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Mohammad Amin Valizade Hasanlouei
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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
Confidentiality of patient information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Report of the results of the clinical study as a published article
When the data will become available and for how long
end of 2018
To whom data/document is available
free access
Under which criteria data/document could be used
as a published article
From where data/document is obtainable
corresponding author
What processes are involved for a request to access data/document
by Email
Comments