

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Email address

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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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

Street address

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

Oroumia University of Medical Sciences

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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

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Position

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Latest degree

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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

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