Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 2026

Effects of synbiotic supplementation on energy and macronutrients homeostasis and muscle wasting of critical care patients: A randomized controlled trial

Protocol summary

Study aim

Evaluating the effects of synbiotic supplementation on energy and macronutrient homeostasis and muscle wasting in critical care patients

Design

This is a prospective, single center, double-blind, parallel randomized controlled trial

Settings and conduct

The setting of the trial will be Edalatian ICU,Emam Reza Hospital,Mashhad,Iran.Except pharmacy company and ward secretary,all patients,researchers,and medical staff will be blind.Energy requirement will be estimated according to ESPEN guideline 2018.In the hight and low nutritional risk patients enteral nutrition will be started by 50% and 30% of estimated calorie respectively.In everyday visits,we will evaluate enteral nutrition tolerance. If tolerated,EN will be increased by 10% each day to achieve calorie target. Before and after the intervention,blood and 24h urine samples will be collected.

Participants/Inclusion and exclusion criteria

Inclusion: Adults aged 18-65 years, ICU admission, stable hemodynamic within 24-48 hour after admission, requiring enteral nutrition via nasogastric tube feeding, and providing the written consent. exclusion:Pregnancy and lactation, any contraindication of EN, any contraindication to placement of nasogastric feeding tube, receiving immunosuppressive treatment, radiotherapy or chemotherapy, hematologic diseases,immune deficiency, transplant recipient, known allergy,cancer or autoimmune diseases, insulin-dependent diabetes, organ failure, sepsis, artificial heart valve or congenital heart disease.

Intervention groups

Lactocare (ZistTakhmir, Iran) capsules 500 mg every 12h for 14 days Placebo capsules (ZistTakhmir, Iran) every 12h for 14 days

Main outcome variables

Enteral feeding tolerance;Energy homeostasis;Protein catabolis;Muscle protein degradation;Muscle protein turnover;Lipolysi;Glucose homeostasis;Inflammatory status;Dysbiosis tatus and luminal integrity;Clinical prognosis;Nutritional status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190227042857N1**
Registration date: **2019-03-17, 1397/12/26**
Registration timing: **prospective**

Last update: **2019-03-17, 1397/12/26**
Update count: **0**

Registration date

2019-03-17, 1397/12/26

Registrant information

Name

Najmeh Seifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 8642

Email address

seifin941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-06, 1398/01/17

Expected recruitment end date

2019-10-09, 1398/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of synbiotic supplementation on energy and macronutrients homeostasis and muscle wasting of critical care patients: A randomized controlled trial

Public title

Symbiotic supplementation effect oncritical care patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged 18-65 years ICU admission stable hemodynamic within 24-48 hour after admission requiring enteral nutrition(EN) via nasogastric tube (NGT) feeding not taking any kind of microbial cell preparations (pre, pro, synbiotic) providing the written consent

Exclusion criteria:

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization will be performed through a stratified sequential randomization plan generated online. Randomization will be stratified by disease severity (APACHEII , 0-35 and 35-70).

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients, researchers, and medical staff will be blind about receiving either synbiotic or placebo capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Mashhad University of Medical Sciences

Street address

Qureishi Building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

91735-951

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.715

Health conditions studied

1

Description of health condition studied

energy and macronutrient homeostasis disturbance-muscle wasting

ICD-10 code

E46

ICD-10 code description

Unspecified protein-calorie malnutrition

Primary outcomes

1

Description

Energy homeostasis

Timepoint

daily

Method of measurement

calorie intake- estimated calorie requirement

2

Description

protein catabolism

Timepoint

7, 14 days after intervention

Method of measurement

nitrogen balance

3

Description

Muscle protein turnover

Timepoint

14 days after intervention

Method of measurement

3MH/ Creatinine ratio in 24h urine

4

Description
Lipolysis
Timepoint
14 days after intervention
Method of measurement
free glycerol in serum

5

Description
Dysbiosis status and luminal integrity
Timepoint
14 days after intervention
Method of measurement
blood Endotoxin levels

Secondary outcomes

1

Description
Infectious complications incidence
Timepoint
daily
Method of measurement
incidence

2

Description
Ventilator- dependent days
Timepoint
14 days after intervention
Method of measurement
number of days

3

Description
Length of ICU stay
Timepoint
14 days after intervention
Method of measurement
number of days

4

Description
Length of hospital stay
Timepoint
14 days after intervention
Method of measurement
number of days

5

Description
28- Day mortality
Timepoint
28 days after intervention
Method of measurement
mortality incidence in 28 days

Intervention groups

1

Description
Intervention group: Lactocare (ZistTakhmir,Tehran, Iran) capsules 500 mg every 12h for 14 days
Category
Treatment - Drugs

2

Description
Control group: placebo every 12h for 14 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Edalatian ICU of Imam Reza Hospital
Full name of responsible person
Alireza Sedaghat
Street address
Imam Reza Hospital, Shariati Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email
sedaghatar@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Research Chancellor, Qureishi Building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91735-951
Phone
+98 51 3841 2081
Email

vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Najmeh Seifi

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Nutrition

Street address

Nutrition Dept.,Medical School, University Paradise,Vakilabad Blvd.

City

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Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3882 7033

Email

seifin941@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Najmeh Seifi

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study protocol will be published in a scientific journal. Clinical study reports will be published in a scientific journal at the end.

When the data will become available and for how

long

Undecided

To whom data/document is available

Undecided

Under which criteria data/document could be used

Undecided

From where data/document is obtainable

Undecided

What processes are involved for a request to access data/document

Undecided

Comments