

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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 high 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 catabolism; Muscle protein degradation; Muscle protein turnover; Lipolysis; Glucose homeostasis; Inflammatory status; Dysbiosis status 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 on critical 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**

Mashhad

**Province**

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

**Position**

PhD candidate

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Najmeh Seifi

**Position**

PhD Candidate

**Latest degree**

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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**