

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of a probiotic supplementation, Lactocare, on gut microbiota in critically ill septic patients admitted to intensive care units

#### Protocol summary

2018-05-09, 1397/02/19

#### Study aim

Effect of a probiotic supplementation, Lactocare, on gut microbiota in critically ill septic patients admitted to intensive care units

#### Design

En Clinical trial with intervention and control groups, with parallel groups, Double-blind, randomized trial

#### Settings and conduct

En All patients admitted to ICUs of Shohada and Imam Reza Hospitals , who are undergoing mechanical ventilation and require the insertion of NGT, will be included in this study. Patients will randomly be assigned to probiotic and control groups. Participants and the person who will analyze the data collected during the study will be kept blind to study groups.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: All critically ill septic patients admitted to intensive care units. Exclusion criteria:

#### Intervention groups

En All patients in intervention group will receive enteral capsules of Lactocare (1 capsule/12h) for 10 days in addition to standard ICU treatment.

#### Main outcome variables

Gut microbiota in critically ill septic patients admitted to intensive care units

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20091012002582N19**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **prospective**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Ata Mahmoodpoor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 116 0888

##### Email address

mahmoodpoora@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2018-06-22, 1397/04/01

#### Expected recruitment end date

2020-09-21, 1399/06/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of a probiotic supplementation, Lactocare, on gut microbiota in critically ill septic patients admitted to intensive care units

#### Public title

Effect of a Lactocare, on gut microbes in critically ill septic patients admitted to intensive care units

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Need for enteral nutrition Age over 18 years old Age

under 70 years old

**Exclusion criteria:**

age under 18 years old age over 70 years old pregnancy lactating previous history of lactocare use Long-term administration of systemic corticosteroid History of alcohol consumption History of intestinal surgery in a recent month

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

Patients are randomly assigned into two groups by block randomization. Randomization is done based on the Grav O tron2.0 software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the participants, the main researcher, the health care staff (doctors, nurses, etc.) responsible for patient care, data collection authorities, those who evaluate the outcome, and those who prepare the draft article. Have been kept blind to the study groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Central Building No. 2, Tabriz University of Medical Sciences, Golghast St,

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166615953

**Approval date**

2017-12-04, 1396/09/13

**Ethics committee reference number**

IR.TBZMED.REC.1396.825

**Health conditions studied**

**1**

**Description of health condition studied**

Other infectious diseases

**ICD-10 code**

B99.8

**ICD-10 code description**

Other infectious disease

**Primary outcomes**

**1**

**Description**

Gut microbiota in critically ill septic patients admitted to intensive care units

**Timepoint**

En days 1th and 10th

**Method of measurement**

PCR of stool

**Secondary outcomes**

**1**

**Description**

En ICU length of stay

**Timepoint**

En during ICU stay

**Method of measurement**

En days that patient is stayed in ICU

**Intervention groups**

**1**

**Description**

Intervention group: En All patients in intervention group will receive enteral capsules of Lactocare (1 capsule/12h) for 10 days in addition to standard ICU treatment.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: All patients in control group will receive standard ICU treatment.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
Shohada hospital ICU

**Full name of responsible person**  
Ata Mahmoodpoor

**Street address**  
Shohada hospital, El-goli street

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mahmoodpoora@tbzmed.ac.ir

### 2

#### Recruitment center

**Name of recruitment center**  
General ICU, Imam Reza hospital

**Full name of responsible person**  
Ata Mahmoodpoor

**Street address**  
Imam Reza hospital, Golgasht street

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Abolghasem Jouyban

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Central Building No. 2, Golgasht Street, Tabriz  
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ajouyban@hotmail.com

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Tabriz 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**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Ata Mahmoodpoor

**Position**  
Director of ICU, Professor

**Latest degree**  
Subspecialist

**Other areas of specialty/work**  
Anesthesiology

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**

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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**

No - There is not 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**

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

**Title and more details about the data/document**

Study will be reported as paper

**When the data will become available and for how long**

Not applicable

**To whom data/document is available**

Not applicable

**Under which criteria data/document could be used**

Not applicable

**From where data/document is obtainable**

Not applicable

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

Not applicable

**Comments**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Roya Ghaemikhiavi

**Position**

Resident of Anesthesiology

**Latest degree**

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**Other areas of specialty/work**

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