Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Study aim
En 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
2018-05-09, 1397/02/19

Registrant information

Name
Ata Mahmoodpoor

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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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 microbs 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
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2

Recruitment center
Name of recruitment center
General ICU, Imam Reza hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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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