Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of probiotic containing lactobacillus, bifidobacterium and streptococus thermophilus administration on inflammatory, coagulation and oxidative factors in critically ill patients with risk of sepsis

Protocol summary

Summary

Sepsis is a major problem in critically ill patients which its pathogenesis consists of an impairment in inflammatory, coagulatory and oxidative pathways. Interleukin 6 (IL-6) and procalcitonin (PCT), protein C, total antioxidant capacity (TAC) and serum levels of malondialdehyde (MDA) change in sepsis. Gastrointestinal tract plays a key role in the pathogenesis of sepsis due to destruction of intestinal barrier function and probiotics seem to have beneficial effects in improvement of critically ill patients and reduction of mortality by changing the intestinal flora. Forty critically ill patients receiving enteral nutrition and expected to stay in ICU for at least 7 days without intestinal ischemia or obstruction will be enrolled in the study. They will be randomly assigned to two groups; the intervention group will receive standard treatment plus 2 sachets of probiotic VSL 3 and the placebo group will receive standard treatment plus 2 sachets of placebo for 7 days. 10 cc of blood will be obtained from each patient to evaluate IL-6, PCT, Protein C, TAC and MDA before the study and on days 4 and 7. APACHE II and SOFA score will be calculated for all patients before the study and on days 4 and 7. Also, 28-day mortality will be evaluated for each patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112143320N6**
Registration date: **2011-12-29, 1390/10/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-12-29, 1390/10/08

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic containing lactobacillus, bifidobacterium and streptococus thermophilus administration on inflammatory, coagulation and oxidative factors in critically ill patients with risk of sepsis

Public title

Effect of probiotic on management of critically ill patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) critically ill patients admitted to the surgical ICU with positive SIRS and APACHE II score 15 to 30; 2) receiving enteral nutrition; 3) aging 18-40 years old; 4) expected to stay in ICU for at least 7 days. Exclusion criteria: 1) pregnant and lactating women; 2) patients who cannot tolerate enteral nutrition; 3) unstable hemodynamic; 4) smoking; 5) immune disorders and diabetes mellitus; 6) intestinal obstruction; 7) intestinal ischemia; 8) Patients who are expected to expire in the next 24 hours; 9) HIV-positive; 10) cancer; 11) bedsore; 12) bone marrow, liver or lung transplantation; 13) short bowel syndrome, pancreatitis and kidney or liver failure; 14) receiving Lactulose, mannitol, and glutamine during the study; 15) patients undergoing GI procedures (endoscopy, resection of the bowel and GI surgeries) during the study.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Glgasht street

City

Tabriz

Postal code

Approval date

2011-10-17, 1390/07/25

Ethics committee reference number

9047

Health conditions studied

1

Description of health condition studied

sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified

Primary outcomes

1

Description

inflammation

Timepoint

days 1, 4, 7

Method of measurement

IL6, PCT

2

Description

Coagulation

Timepoint

days 1, 4, 7

Method of measurement

protein C

3

Description

oxidative stress

Timepoint

days 1, 4, 7

Method of measurement

TAC, MDA

Secondary outcomes

1

Description

mortality

Timepoint

days 1, 4, 7

Method of measurement

being live or dead

Intervention groups

1

Description

2 Sachets of probiotic VSL 3 (containing lactobacillus, bifidobacterium and streptococus species)/day for 7 days

Category

Treatment - Drugs

2

Description
2 sachet of placebo/day for 7 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
ICU- Shohada hospital
Full name of responsible person
Ata Mahmoodpoor
Street address
El-goli street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostadrahimi
Street address
Golgasht street
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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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty