Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effects of Postbiotic supplementation on Gut microbiota profiles and clinical factors in CVA patients under mechanical ventilation admitted to intensive care unit: a clinical trial

Protocol summary

Study aim

Effect of Posbiotics supplement on intestinal microbiota and clinical outcomes in patients with stroke and under mechanical ventilation hospitalized in the ICU

Design

Clinical trial study with parallel groups, double-blind, with placebo, one control group, randomized using blocking method, phase 3, on 60 patients

Settings and conduct

Eligible patients to enter the study are selected from among those who refer to Imam Reza Hospital (AS), which is under the supervision of Kermanshah University of Medical Sciences. 120 patients suffering from cerebral stroke and under mechanical ventilation admitted to the ICU, whose illness was confirmed by the relevant specialist (in Imam Reza (AS) hospital, which is under the supervision of Kermanshah University of Medical Sciences), after completing the consent form by the companion First-grade patients will enter the study.

Participants/Inclusion and exclusion criteria

Patients suffering from stroke and under mechanical ventilation hospitalized in the intensive care unit, aged eighteen years and older; BMI = 18.5-30 will be included in the study, but pregnancy; Weakening of the immune system for any reason, receiving immune system suppressants, heart valve replacement; Vascular graft is one of the exclusion criteria.

Intervention groups

Patients in the first group will be prescribed Lactobacillus paracasei postbiotic supplement (containing short-chain fatty acids and exopolysaccharides) in the amount of 2000 mg, and in the second group, a placebo containing maltodextrin will be prescribed one sachet per day for 7 days.

Main outcome variables

Duration of hospitalization in ICU, Firmicutes Bacteroidetes Ratio), BUN, Cr, TAC and MDA levels, reduction in the incidence of ventilator-associated pneumonia and the survival rate of patients in the ICU department, duration of hospitalization, duration of Intubation and 28-day mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180712040438N7**
Registration date: **2022-12-06, 1401/09/15**
Registration timing: **prospective**

Last update: **2022-12-06, 1401/09/15**
Update count: **0**

Registration date

2022-12-06, 1401/09/15

Registrant information

Name

Jalal Moludi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Postbiotic supplementation on Gut microbiota profiles and clinical factors in CVA patients under mechanical ventilation admitted to intensive care unit: a clinical trial

Public title

The effects of Postbiotic in CVA patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with stroke and under mechanical ventilation admitted to the intensive care unit Age eighteen and older BMI= 18.5- 30 Written consent from relatives The patient has a tracheal tube and is under mechanical ventilation and it continues for 72 hours, and 48 hours have not passed since the patient's intubation and feeding should start within the next 24 hours.

Exclusion criteria:

pregnancy Weakening of the immune system for any reason receiving heart valve replacement vascular graft immune system suppressants

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study is block randomization, the random sequence is generated by a statistical consultant. The registration of people is done by the project manager. Allocating people to groups is done by the statistics consultant. The team leader is different from the outcome assessor, and the team leader is not involved in the process of collecting information and evaluating the outcome, and this work will be done by trained evaluators. For random allocation of people, 6 blocks with 4 permutations will be created in the following order: 1=AABB 2=ABAB 3=ABBA 4=BABA 5=BBAA 6=BAAB where A represents the postbiotic group and B represents the placebo group. Then, based on the numbers in the random table, a number will be chosen randomly, and based on the last digit on the right, one of the groups will be used to determine the sequence of randomization. It should be noted that if the number on the right side is zero or 7 to 9 when choosing a random number, that number will not be considered and a random number will be selected again. This work will continue until all 104 people are assigned to two groups. It should be noted that this method will prevent the unbalance of the two groups as well as the identification of the randomization sequence, and the ratio of 1:1 will be observed in the two groups. It is registered and the cards are placed in the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box respectively. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

This clinical trial will be blinded at 3 levels (patient, outcome assessor, analyst). For blinding, it will be arranged that a code will be assigned to each drug package, which can only be identified by an independent person and the patient, the person who collects the data and the statistical analyzer, from what judgment the patient has taken. will be unaware.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Faculty of Nutrition and Food Technology, Next to Farabi Hospital, Kermanshah, Iran

City

kermanshah

Province

Kermanshah

Postal code

6719851552

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.KUMS.REC.1401.327

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
164
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
Duration of hospitalization in ICU
Timepoint
From the beginning of the study to the 28th day
Method of measurement
patient file

Secondary outcomes

1

Description
Improving the composition of the intestinal microbiota
Timepoint
Before and after the intervention
Method of measurement
Via real time PCR

2

Description
BUN
Timepoint
At the time of patient admission, day 7, day 14 and day 28
Method of measurement
Enzymatic method

3

Description
Cr
Timepoint
At the time of patient admission, day 7, day 14 and day 28
Method of measurement
Enzymatic method

4

Description
serum levels of hs-CRP
Timepoint
At the beginning of admission and on the 28th day
Method of measurement
ELISA

5

Description
serum levels of ESR
Timepoint
At the beginning of admission and on the 28th day
Method of measurement
ELISA

6

Description
serum levels of interleukin 6
Timepoint
At the beginning of admission and on the 28th day
Method of measurement
ELISA

7

Description
serum levels of interleukin 10
Timepoint
At the beginning of admission and on the 28th day
Method of measurement
ELISA

8

Description
Improvement of nutritional status
Timepoint
NUTRIC scoring system
Method of measurement
At the beginning of admission and on the 28th day

9

Description
TAC
Timepoint
At the beginning of admission and on the 28th day
Method of measurement
ELISA

10

Description
MDA
Timepoint
At the beginning of admission and on the 28th day
Method of measurement
ELISA

11

Description
survival rate of patients in the ICU
Timepoint
From the beginning of admission to the 28th day
Method of measurement
Using patient records

12

Description
Duration of hospitalization
Timepoint
From the beginning of admission to the 28th day
Method of measurement
Using patient records

13

Description
Duration of intubation
Timepoint
From the beginning of admission to the 28th day
Method of measurement
Using patient records

14

Description
mortality rate
Timepoint
From the beginning of admission to the 28th day
Method of measurement
Using patient records

Intervention groups

1

Description
Intervention group: Patients in the first group will be prescribed Lactobacillus paracasei postbiotic supplement (containing short-chain fatty acids and exopolysaccharides) in the amount of 2000 mg per day for 7 days.
Category
Treatment - Drugs

2

Description
Control group: Patients in the second group of placebo containing maltodextrin will be prescribed one sachet per day for 7 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Jalal Moloudi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Vice Chancellor for Research No 2 Central Building, Kermanshah
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Province
Kermanshah
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2589631478
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Email
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Jalal Moludi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
Information related to the main results will be shared
When the data will become available and for how long
Accessibility to data is possible 8 months after publication
To whom data/document is available
The data will only be available for people working in academic institutions
Under which criteria data/document could be used
The data of the present study will only be accessible by other researchers, for conducting Meta analysis
From where data/document is obtainable
Dr. Jalal Mokudi, Faculty of Nutrition and Food Sciences, Kermanshah University of Medical Sciences Email: jmoludi@yahoo.com 0098 9399516760
What processes are involved for a request to access data/document
The applicator can send a request to the person responsible for the study by email and within 10 days the document will be sent to the requesting person
Comments