Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of probiotic administration of interleukins 6 and 10 levels in poisoned patients admitted to ICU of Loghman hospital in 1400

Protocol summary

Study aim

The aim of the study was the evaluation of the effect of probiotic administration of interleukins 6 and 10 levels in poisoned patients admitted to the ICU of Loghman hospital in 1400.

Design

Clinical trial with two intervention groups with parallel groups of double-blind randomized phase 3 on 100 patients. Creating randomization will be done as a simple randomization and by preparing black and white beads of the same shape and size.

Settings and conduct

Patients with poisoning and hospitalized in the special care department of Loqman Hakim hospital in Tehran will be selected and will be divided into two groups receiving probiotics and placebo by simple randomization and through colored beads. Probiotic group, received 2 probiotic capsules daily up to 7 days and the placebo group will receive the same placebo daily for 7 days. The level of interleukins 6 and 10 was checked before treatment and one week later, and the results of these changes and the significance or not of these statistics can be checked and concluded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: poisoned patients admitted to the ICU receiving enteral nutrition and staying in the ICU for at least seven days. Exclusion criteria: patients with enteral feeding intolerance, intestinal obstruction, kidney failure, pancreatitis, short bowel syndrome, a history of chemotherapy.

Intervention groups

Patients with poisoning and hospitalized in ICU are divided into two groups, control group and intervention group, the intervention group received placebo once every 8 hours for 7 days and the control group received two probiotic capsules every 8 hours for 7 days as gavage.

Main outcome variables

IL-6 and IL-10

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210720051946N5**
Registration date: **2022-10-06, 1401/07/14**
Registration timing: **prospective**

Last update: **2022-10-06, 1401/07/14**
Update count: **0**

Registration date

2022-10-06, 1401/07/14

Registrant information

Name

Peyman Erfan Talab Evini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5102 5000

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peyman1346erfan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of probiotic administration of interleukins 6 and 10 levels in poisoned patients admitted to ICU of Loghman hospital in 1400

Public title

Evaluation efficacy of probiotics on some inflammatory factors of ICU cases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with poisoning Admission to the ICU Receive enteral nutrition ICU admission for at least seven days

Exclusion criteria:

Intestinal obstruction Renal failure Pancreatitis Short bowel syndrome History of chemotherapy

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization type will be simple randomization. 100 beads of the same shape and size and with black and white colors will be selected. Then these 100 beads are mixed and thrown into a non-transparent bag. When the patient visits, according to the conditions of entering the study, the researcher will remove a bead from the bag, and if the bead is black, the patient will enter the control group, and if the bead is white, the patient will enter the intervention group. This bead will be stored inside another bag. This will be repeated 100 times.

Blinding (investigator's opinion)

Double blinded

Blinding description

People from the research team who are responsible for the selection and randomization of patients will not be included in the other stages of the research, especially the examination of people in terms of dependent variables. Also after consent form approval, neither patients nor their companions were informed about patients group of control and intervention. Also in control group we will use placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Aarabi Ave, Velenjak, Tehran City

City

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Province

Tehran

Postal code

1333635445

Approval date

2022-08-15, 1401/05/24

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.299

Health conditions studied

1

Description of health condition studied

Intoxication

ICD-10 code

A05

ICD-10 code description

Other bacterial foodborne intoxications, not elsewhere classified

Primary outcomes

1

Description

IL-6

Timepoint

Before treatment and after complete period of treatment

Method of measurement

kgf kit

2

Description

IL-10

Timepoint

Before treatment and after complete period of treatment

Method of measurement

kgf kit

Secondary outcomes

empty

Intervention groups

1

Description
Control group: For seven days, TDS received placebo
Category
Placebo

2

Description
Intervention group: For seven days TDS received two probiotic capsules as gavage.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim hospital
Full name of responsible person
Dr Peyman Erfan Talab Evini
Street address
Loghman Hospital kamali st. Kargar st, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarbi
Street address
No. 2, Shahid Aarabi St.,, Yemen St., Shahid Chamran Highway., Tehran city
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Peyman Erfan Talab Evini
Position
Assistant professor
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Toxicology
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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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