

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Email address

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

Tehran

##### 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

#### City

Tehran

#### Province

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#### Postal code

1333635445

#### Phone

+98 21 5541 9005

#### Email

peyman1346erfan@sbmu.ac.ir

## 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

#### City

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#### Province

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#### Phone

+98 21 2243 9780

#### Email

info@sbmu.ac.ir

#### 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

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Toxicology

#### Street address

Loghman Hospital, kamali st, Kargar st, Tehran, Iran

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Peyman Erfan Talab Evini

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Assistant professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Peyman Erfan Talab Evini  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Toxicology  
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Loghman Hospital, kamali st, Kargar st, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran

**Postal code**  
1333635445  
**Phone**  
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**Email**  
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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