

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Investigating the effect of an acidophilic *Lactobacillus brevis* strain enriched with selenium on bedsores of ICU patients

Protocol summary

Study aim

Investigating the effect of an acidophilic *Lactobacillus brevis* strain enriched with selenium on bedsores of ICU(Intensive care unit) patients of Shahid Bahonar Medical Center, Kerman

Design

Initially, the initial sample size is 40 patients and they are divided into two groups of 20 subjects and controls. It is an intervention study or clinical trial During hospitalization in the ICU(Intensive care unit) department, 109 CFU of Selenium-enriched *Lactobacillus brevis* is administered once a day for 2 weeks.

Settings and conduct

It is performed in a double blind method in the ICU(Intensive care unit) department of Shahid Bahonar Medical Center in Kerman, and the patient, clinical caregiver, and outcome evaluator are not informed about the type of capsule consumed.

Participants/Inclusion and exclusion criteria

The criteria for entering the study are having a bed sore (stage 1 and 2), not receiving other probiotics, being hospitalized in the ICU(Intensive care unit) department of Bahonar Hospital, not having sepsis, pneumonia, other active infection, and known immunodeficiency. The criterion for exiting the plan is the patient's exit from the ICU and anesthesia service of Bahonar Hospital

Intervention groups

In this plan, we have a control group (placebo) and a study group at the same time, and the intended placebo substance is maltodextrin.

Main outcome variables

bedsore

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221221056887N2**

Registration date: **2023-05-12, 1402/02/22**

Registration timing: **prospective**

Last update: **2023-05-12, 1402/02/22**

Update count: **0**

Registration date

2023-05-12, 1402/02/22

Registrant information

Name

Farshid Ataollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 8942

Email address

farshid.ataollahi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of an acidophilic *Lactobacillus brevis* strain enriched with selenium on bedsores of ICU patients

Public title

Investigating the effect of an acidophilic *Lactobacillus*

brevis strain enriched with selenium on bedsores of ICU patients of Shahid Bahonar Medical Center, Kerman

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

having bedsores (stage 1 and 2) Not receiving other probiotics Being hospitalized in the ICU department of Bahonar Hospital Not having sepsis, pneumonia, other active infection and known immunodeficiency

Exclusion criteria:

The patient was discharged from the ICU and anesthesia service of Bahonar Hospital

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

After examining the patients in terms of the criteria for entering the study and obtaining informed consent, the total number of people eligible to enter the study will be divided into two equal groups of 40 people, and the placement of people in these two groups will be done by block randomization along with the blinding process. It was like this that in the randomization, people are placed in two groups randomly and completely randomly, and in order to equalize the number of people in the two groups, block randomization will be done if needed (if the total sample size at the beginning of the study for If block randomization is not available, then randomization is used by the random number table method in such a way that we divide the number of people into two groups based on the random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study has been double-blind in that the patient himself does not know the type of capsule received, and also the treatment staff such as the clinical supervisor and project researchers such as the evaluator of the investigated factors and the outcome researcher do not know the type of capsule prescribed and only based on Capsule number 1 and 2 are prescribed and will be determined at the time of data analysis

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Jahad Blvd. Ebn Sina Avenue, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-05-01, 1402/02/11

Ethics committee reference number

IR.KMU.REC.1402.038

Health conditions studied

1

Description of health condition studied

bedsores

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

Primary outcomes

1

Description

Bedsore

Timepoint

The entire duration of drug administration

Method of measurement

Observation and examination of the wound by the researcher (wound healing time, wound dimensions and wound stage)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: studied probiotic (probiotic capsule - containing 109 cfu of Lactobacillus isolated from dairy and edible products, which is cultured in an environment containing selenium salt to be enriched with selenium,

and after laboratory confirmation of the bacteria, it is used in the study for human use - manufacturing Kerman University of Medical Sciences - Iran, which is prescribed to the patient once a day for 2 weeks, and if the patient is intubated, it is given to the patient through the NG tube, which is installed in the ward for patients with reduced level of consciousness.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Placebo capsule or placebo contains 50 grams of maltodextrin made in Iran, which is prescribed to the patient once a day for 2 weeks, and if the patient is intubated, it is inserted through the NG tube in the ward for patients with reduced level of consciousness. is given to the patient)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar hospital

Full name of responsible person

Farshid Ataollahi

Street address

Qorani St. - Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

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Email

bahonarhospital@kmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Biotechnology Development Headquarters

Full name of responsible person

Ruhollah Dehghani Firouzabadi

Street address

scientific and technological department of presidential office, No,. 20, Ladan alley, North Sheikh Bahayee St., MollaSadra St., Vanak Sq.

City

Tehran

Province

Tehran

Postal code

1991745681

Phone

+98 24 83539

Email

pr@isti.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Biotechnology Development Headquarters

Proportion provided by this source

50

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

Other

2

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

Street address

Ebn-e-Sina St.,Jahad Blvd.,

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Province

Kerman

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Phone

+98 34 3226 3719

Email

kmu@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

50

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

Kerman University of Medical Sciences

Full name of responsible person

Farshid Ataollahi

Position

Non-faculty general practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Qaraney St, Next to Shahid Bahonar Hospital, Upper Floor Of Pharmacy No.2 , Kerman, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Farshid Ataollahi

Position

Non-faculty general practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Farshid Ataollahi

Position

Non-faculty general practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

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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

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

No - There is not a plan to make this available

Title and more details about the data/document

Project data will be published without mentioning personal information and identification of study subjects

When the data will become available and for how long

Access starts from the publication of the final report

To whom data/document is available

The data that can be published is published in the form of a final report and is available to everyone

Under which criteria data/document could be used

The data that can be published will be announced in the final report of the plan

From where data/document is obtainable

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

What processes are involved for a request to access data/document

After the completion of the project (1 year)

Comments