

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of probiotics as an adjunctive therapy with mortality outcome, length and rate of hospitalization in Intensive Care Unit in patients with COVID-19

Protocol summary

Study aim

Investigation the effect of probiotics as an adjunctive therapy with mortality outcome, length and rate of hospitalization in Intensive Care Unit in patients with COVID-19

Design

This three-blind and parallel clinical trial study will be conducted on two groups of 30 patients with corona virus hospitalized in Razi Medical Education Center in Rasht.

Settings and conduct

Corona patients hospitalized in Razi Hospital, Rasht, in a three-blind manner and in two groups of 30 people randomly receive standard treatment with or without Lactocare probiotic.

Participants/Inclusion and exclusion criteria

Inclusion: Patients who are hospitalized due to COVID-19. Patients should be 18 years old and older. Patients should have clinical symptoms and pneumonia of covid in chest radiography or CT scan. Patients should not participate in other clinical trials at the same time. exclusion: COPD, cancer, Liver disease or cirrhosis

Intervention groups

Experimental group standard treatment and lactocare control group standard treatment and placebo

Main outcome variables

Admission to ICU, need to intubation, mortality, vital signs, cough, dyspnea, diarrhea, abdominal pain, length of hospitalization, o2 saturation, Hb, Platelet, ESR, CRP, WBC, lymphocyte, NLR, CPK, ALT, AST, fibrinogen, D-dimer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220124053820N1**

Registration date: **2022-09-19, 1401/06/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-19, 1401/06/28**

Update count: **0**

Registration date

2022-09-19, 1401/06/28

Registrant information

Name

Shadi Dehghanzadeh

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotics as an adjunctive therapy with mortality outcome, length and rate of hospitalization in Intensive Care Unit in patients with COVID-19

Public title

Investigation the effect of probiotics in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are hospitalization due to COVID-19. Patients should be 18 years old and older. Patients should have clinical symptoms and pneumonia of covid in chest radiography or CT scan. Patients should not particitaion in other clinical trials at the same time.

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To equalize the number of patients in two groups, block randomization method is used. For randomization, random fixed block method is used in blocks of 4. In such a way that two samples from the experimental group and two samples from the control group are allocated in each block.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients in two groups do not know which group they are in. For this reason, placebo is used to pay attention to the psychological aspect and acceptance of the patient. The infectious disease specialist who is in charge of treating the patients also does not know which group the patient belongs to. The patient assessor, who collects data related to the disease and outcomes, does not know which group the patient belongs to. Patients (experimental group or control group) receive the medicine in sealed envelopes that are coded. Coding is done by one of the collaborators of the project and the patient, doctor and evaluator are blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Thics committee of Lahijan Islamic azad University

Street address

Islamic azad University Lahijan branch, 45 meter university Blvd, lahijan

City

lahijan

Province

Guilan

Postal code

44169-39515

Approval date

2022-06-12, 1401/03/22

Ethics committee reference number

IR.IAU.LIAU.REC.1401.027

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

COVID-19

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Need to admission to ICU

Timepoint

Daily

Method of measurement

By evaluator using patient's file and ward's information

2

Description

Need to intubation

Timepoint

Daily

Method of measurement

By evaluator using patient's file and ward's information

3

Description

Mortality

Timepoint

Daily

Method of measurement

By evaluator using patient's file and ward's information

4

Description

Vital signs

Timepoint

Three times a day

Method of measurement

By evaluator using mercury sphygmomanometer and thermometer

5

Description

Symptoms consisting cough, dyspnea, diarrhea, abdominal pain

Timepoint

Daily

Method of measurement

By evaluator asking patient and patient's file

6

Description

O2 saturation

Timepoint

Three times a day

Method of measurement

By evaluator using pulse oxymeter

7

Description

laboratories tests: Hb, Platelet, ESR, CRP, WBC, lymphocyte, NLR, CPK, ALT, AST, fibrinogen, D-dimer

Timepoint

Daily

Method of measurement

By Razi Hospital Laboratory

8

Description

Length of hospitalization

Timepoint

Daily

Method of measurement

By evaluator by patient's file

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group receives probiotic Lactocare 500 mg capsules produced by Zist Takhmir company twice a day in addition to the treatment prescribed by the infectious disease specialist.

Category

Treatment - Drugs

2

Description

The control group receives the treatment prescribed by the infectious disease specialist along with the placebo capsules produced by Zist Takhmir company twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Dr Shadi deghanzadeh

Street address

Rasht Islamic Azad University, Pole Taleshan, Rasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Rasht Islamic Azad University and Zist Takhmir company

Full name of responsible person

Dr Alireza Seidavi

Street address

Rasht Islamic Azad University, Pole Taleshan, Rasht

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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

Research deputy of Rasht Islamic Azad University and Zist Takhmir company

Proportion provided by this source

20

Public or private sector

Private

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

Rasht Islamic Azad University

Full name of responsible person

Dr Shadi dehghanzadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Specialist

Other areas of specialty/work

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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