

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Investigation of the effect of Lactocare® synbiotic on the prevention of COVID-19 infection in the staff of emergency department

Protocol summary

Study aim

Investigation of the effect of Lactocare® synbiotic on the prevention of COVID-19 infection in the staff of emergency department

Design

Clinical trial with control group and parallel groups, randomized and double blind

Settings and conduct

This clinical trial is conducted on 80 members of the personnel of the emergency department of Imam Reza hospital including physicians and nurses who work where patients infected by COVID-19 are hospitalized. These participants are randomly assigned to two groups of control and treatment. At the beginning of the study, patients are examined by a specialist and take antibody test and their data including their personal and professional information are recorded. Patients and outcome assessors are unaware of the groupings.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being a member of the personnel of the emergency department of Imam Reza hospital; active presence in the wards where patients with COVID-19 are hospitalized. Exclusion criteria: history of clinical or laboratory diagnosis with COVID-19

Intervention groups

Intervention group: In this group, patients will receive a Lactocare® synbiotic capsule daily for a month. Control group: Patients in this group will receive a capsule as placebo (with the same shape, smell, design and color) containing no probiotic daily for one month.

Main outcome variables

Fever, findings of CT scan and CXR, number of lymphocytes, WBC and infection by COVID-19, cough and sore throat, nausea, vomiting and diarrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101020004976N6**

Registration date: **2020-07-18, 1399/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-18, 1399/04/28**

Update count: **0**

Registration date

2020-07-18, 1399/04/28

Registrant information

Name

Hamid Ahanchian

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2469

Email address

ahanchianh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-14, 1399/02/25

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of Lactocare® synbiotic on the prevention of COVID-19 infection in the staff of emergency department

Public title

The effect of Lactocare® synbiotic on the prevention of COVID-19 infection in the staff of emergency department

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being a member of the personnel (including physicians and nurses) of the emergency department of Imam Reza hospital Active presence in the wards where patients with COVID-19 are hospitalized

Exclusion criteria:

History of clinical or laboratory diagnosis with COVID-19

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants are not aware of the type of treatment and the intervention. Also, outcome assessors are unaware of the grouping. Patients in the control group receive placebo drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mashhad university of Medical Sciences

Street address

Ghoreyshi Building, Daneshgah street, Mashhad Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.MUMS.REC.1399.240

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

U07.1

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Fever

Timepoint

Before during and after treatment

Method of measurement

Thermometer

2

Description

Findings of CT scan and CXR

Timepoint

After treatment

Method of measurement

CT scan and CXR machines

3

Description

Number of lymphocytes

Timepoint

Before and after treatment

Method of measurement

Biochemical tests

4

Description

WBC

Timepoint

Before and after treatment

Method of measurement

Biochemical tests

5

Description

Infection by COVID-19

Timepoint

Before treatment, during treatment if symptoms appear and at the end of treatment

Method of measurement

PCR and antibody tests

6

Description

Cough and sore throat

Timepoint

Before, during and after treatment

Method of measurement

Clinical observations

7

Description

Nausea, vomiting and diarrhea

Timepoint

Before, during and after treatment

Method of measurement

Clinical observations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients will receive a Lactocare® synbiotic capsule daily for a month.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive a capsule as placebo (with the same shape, smell, design and color) containing no probiotic daily for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dr Hamid Ahanchian

Street address

Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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34591357

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Ahanchian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Hamid Ahanchian

Position

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Web page address

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments

After sending a request email to the corresponding author, data will be sent in 1 month.