

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

The effect of Lactocare synbiotic on clinical manifestations, inflammatory and non-inflammatory markers in hospitalized covid-19 patients

Protocol summary

Study aim

Evaluation of the effect of synbiotic supplementation on clinical manifestations, inflammatory and non-inflammatory markers in hospitalized Covid-19 patients compared with placebo

Design

Clinical trial with control group (placebo), with parallel groups, double-blind, randomly blocked, phase 3 on 60 patients. The www.sealedenvelope.com was used to generate a blocked random allocation sequence.

Settings and conduct

This study is a randomized clinical trial and patients admitted with Covid 19 in Ghaem Hospital in Mashhad, after obtaining informed consent, patients are randomly placed in one of two intervention groups or placebo. Double-blind randomization will be done by packets in the package. According to the pre-designed checklist, patients in both groups will be followed up for 14 days from the time of admission, and clinical signs, inflammatory and non-inflammatory markers will be taken from patients on the first day and the fourteenth day of follow-up.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Conscious consent Hospitalized patients with Covid 19 Age category 18 years and above
Exclusion criteria: Pregnancy and lactation
Hospitalization in the ICU

Intervention groups

In the intervention group, patients, take two synbiotic daily for 14 days. In the placebo group, patients take two placebo daily for 14 days.

Main outcome variables

Levels of inflammatory factors CRP, ESR and IL-6 as well as ALT, AST, ALP, CBC, and Creatinine on the first and fourteenth day of follow-up. Evaluation of clinical symptoms such as cough, fever, rapid breathing, sore throat, whole body pain, shortness of breath, SPO2 with and without oxygen, weakness and lethargy, abdominal pain, chest pain and gastrointestinal symptoms

(diarrhea, vomiting and nausea) Daily until the end of the follow-up.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210531051459N1**

Registration date: **2021-10-02, 1400/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-02, 1400/07/10**

Update count: **0**

Registration date

2021-10-02, 1400/07/10

Registrant information

Name

Mona Kabiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 7403

Email address

kabirimn@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-27, 1400/07/05

Expected recruitment end date

2022-04-25, 1401/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Lactocare synbiotic on clinical manifestations, inflammatory and non-inflammatory markers in hospitalized covid-19 patients

Public title

The effect of synbiotic in hospitalized covid-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hospitalized patients with definitive diagnosis of Covid 19 using PCR or CT scan Conscious consent to participate in the study Age category 18 years and above

Exclusion criteria:

Acute pancreatitis Pregnancy and lactation Having autoimmune diseases and taking immunosuppressants or drugs used to reject transplants Taking supplements containing probiotics and prebiotics in the last three months Hospitalization in the ICU Patients treated with herbal medicines or other traditional medicine methods Dialysis patients Having a history of allergies to synbiotics Dissatisfaction with participating in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization type: Block Randomization unit: individual Randomization tool: Random number table using www.sealedenvelope.com How to create a random sequence: At www.sealedenvelope.com, the randomization section, after selecting create a list, specifies the number of groups, block sizes and list length, and accordingly, presents the list randomization. Allocation Concealment: Sealed envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants did not know the type of treatment they received. Also, patient clinicians, physicians, and outcome assessors are unaware of how patients are grouped and use medication or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghaem Hospital, Ahmad Abad Ave., Mashhad

City

Mashhad

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Razavi Khorasan

Postal code

99199-91766

Approval date

2021-08-03, 1400/05/12

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.338

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

U07.1 COVID-19, virus identified

Primary outcomes**1****Description**

The level of CRP inflammatory marker

Timepoint

At the beginning of the study and fourteen days after taking the capsule

Method of measurement

Blood test

2**Description**

The level of IL-6 inflammatory cytokine

Timepoint

At the beginning of the study and fourteen days after taking the capsule

Method of measurement

ELISA

3**Description**

ESR level

Timepoint

At the beginning of the study and fourteen days after taking the capsule

Method of measurement

Blood test

Secondary outcomes**1****Description**

ALT level

Timepoint

At the beginning of the study and fourteen days after taking the capsule

Method of measurement

Blood test

2**Description**

AST level

Timepoint

At the beginning of the study and fourteen days after taking the capsule

Method of measurement

Blood test

3**Description**

ALP level

Timepoint

At the beginning of the study and fourteen days after taking the capsule

Method of measurement

Blood test

4**Description**

Creatinine level

Timepoint

At the beginning of the study and fourteen days after taking the capsule

Method of measurement

Blood test

5**Description**

Complete Blood Count (CBC)

Timepoint

At the beginning of the study and fourteen days after taking the capsule

Method of measurement

Blood test

6**Description**

Cough

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

7**Description**

Fever

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

8**Description**

Breathing rate

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up (number of breaths per minute)

9**Description**

Sore throat

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

10**Description**

Generalized body pain

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

11**Description**

Dyspnea

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

12**Description**

SPO2

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

13**Description**

Weakness and lethargy

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

14**Description**

stomach pain

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

15**Description**

Chest pain

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

16**Description**

Gastrointestinal symptoms (diarrhea, vomiting and nausea)

Timepoint

Daily (first day to fourteenth day of intervention)

Method of measurement

Clinical check up

Intervention groups**1****Description**

Intervention group: In the intervention group, hospitalized patients with Covid 19, in addition to standard treatment (Remdesivier, and glucocorticoids such as dexamethasone, methylprednisolone, and prednisolone), take two supplements of Lactocarb synobiotic daily after meals for 14 days. Lactocarb capsules contains beneficial and safe bacterial strains along with prebiotic fructooligosaccharide. Lactocarb capsule made by Zist Takhmir Company is gluten free and its CFU is 10^9 .

Category

Treatment - Drugs

2**Description**

Control group: In the control group (placebo), hospitalized patients with Covid 19 in addition to standard treatment (Remdesivier, and glucocorticoids such as dexamethasone, methylprednisolone, and prednisolone), take two placebo daily after meals for 14 days. The placebo is exactly the same color, shape, weight, and packaging as the Lactocarb capsule. Placebo capsules are also purchased from Zist Takhmir Company.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem hospital

Full name of responsible person

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Web page address<https://quaem.mums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Web page address<https://v-research.mums.ac.ir/>**Grant name****Grant code / Reference number**

992359

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
Mona Kabiri
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Nanotechnology
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Person responsible for scientific inquiries

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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

No - There is not 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

The potential data can be shared after unidentified individuals.

When the data will become available and for how long

Access period starts 9 months after the published results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The use of data and its analysis is allowed by mentioning the source.

From where data/document is obtainable

Email the author of the article to receive the data.

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

The processes that researcher who request data go through will include a letter of request from the person, a

letter of request from the center or university of origin, and acceptance of the destination university to receive the information.

Comments