Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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

Province
Razavi Khorasan

Postal code
۹۹۱۹۹-۹۱۷۶۶

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. Lactocare capsules contains beneficial and safe bacterial strains along with prebiotic fructooligosaccharide. Lactocar 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 Lactocare 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
Mona Kabiri
Street address
Ghaem hospital, Ahmad Abad Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
۹۹۱۹۹-۹۱۷۶۶
Phone
+98 51 3841 7403
Fax
Email
Kabirimn@mums.ac.ir
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
Dr. Mohsen Tafaghodi
Street address
Vice Chancellor for Research and Technology, Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
vcresraech@mums.ac.ir
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

Street address

Clinical Research Development Unit, First Floor, Narjes building, Ghaem hospital, Ahmad Abad Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۹۱۹۹-۹۱۷۶۶

Phone

+98 51 3841 7403

Email

kabirimn@mums.ac.ir

Web page address

https://crdc.mums.ac.ir/

Person responsible for scientific 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

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Phone

+98 51 3841 7403

Email

Kabirimn@mums.ac.ir

Web page address

https://crdc.mums.ac.ir/

Person responsible for updating data

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

Street address

Clinical Research Development Unit, First Floor, Narjes building, Ghaem hospital, Ahmad Abad Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۹۱۹۹-۹۱۷۶۶

Phone

0098518417403

Email

Kabirimn@mums.ac.ir

Web page address

https://crdc.mums.ac.ir/

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