

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the complementary effect of synbiotic adjuvant on inflammatory markers and clinical manifestations in patients with COVID-19

Protocol summary

Study aim

Evaluation of the effect of synbiotic supplementation on inflammatory markers (CRP, ESR, IL-6, CBC) and clinical manifestations before and 8 weeks after treatment in patients with COVID-19

Design

Clinical trial with parallel control group, double-blind, randomized, phase 0 on 80 patients. Stratified block randomization method was used for randomization.

Settings and conduct

In this interventional study, patients with COVID-19 are studied; which are randomly divided into case and control groups. These patients receive probiotic or placebo treatment for two months. All patients are blinded to the type of intervention. They do not know about receiving medication or placebo.

Participants/Inclusion and exclusion criteria

People between the ages of 18-70; basic literacy; writing ability and memory strength; mental conditions to continue attending the study and completing the consent form are studied. People who participate in other clinical trial studies at the same time, other acute and serious illnesses; regular and periodic use of certain dietary supplements or special diets; taking other probiotic supplements; receiving full dose corticosteroids; people with pancreatitis, sepsis, dialysis, central vein and chronic diarrhea; people waiting for abdominal surgery; people with acute immune deficiencies such as AIDS; people with short bowel syndrome or at risk for mesenteric ischemia and pregnant women or breastfeeding mothers are excluded from the study.

Intervention groups

Case group: In this group, patients take two synbiotic adjuvant capsules (after lunch) every day for 2 months of intervention. Control group: In this group, patients take two placebo capsules every day (after lunch) for 2 months of intervention.

Main outcome variables

Clinical symptoms; Inflammatory markers (IL-6, CRP, ESR, CBC, ...)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200923048815N1**

Registration date: **2020-10-15, 1399/07/24**

Registration timing: **prospective**

Last update: **2020-10-15, 1399/07/24**

Update count: **0**

Registration date

2020-10-15, 1399/07/24

Registrant information

Name

Majid Aghadavood Marnani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

majid.aghadavood@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the complementary effect of synbiotic adjuvant on inflammatory markers and clinical manifestations in patients with COVID-19

Public title

The effect of synbiotic on inflammatory markers and clinical manifestations in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-70 years old Basic literacy Writing ability and healthy memory Mental conditions for continuing to attend the study and completing the consent form

Exclusion criteria:

Simultaneous participation in other clinical trial studies Having other acute and serious diseases Regular and periodic consumption of special dietary supplements or special diets Taking other probiotic supplements Receive corticosteroids in full dose People with pancreatitis, sepsis, dialysis, central venous and chronic diarrhea People waiting for abdominal surgery People with acute immune deficiencies such as AIDS People with short bowel syndrome or are at risk for mesenteric ischemia Pregnant women and mothers who are breastfeeding.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomization method will be used to allocate participants to the groups with a 1:1 allocation using random allocation software (RAS). Similar sealed envelopes will be used to conceal the allocation in a sequentially numbered package.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants, patient's clinical caregiver, outcome assessor, and data analyst were unaware of drug or placebo use.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Soffeh Blvd, Alzahra Hospital

City

Esfahan

Province

Isfahan

Postal code

8174675731

Approval date

2020-05-30, 1399/03/10

Ethics committee reference number

IR.MUI.MED.REC.1399.204

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

Coronavirus infection

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

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

inflammatory markers

Timepoint

Before and 8 weeks after start of intervention

Method of measurement

Biochemical analysis

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

Clinical symptoms

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Comment by physician

Intervention groups

1

Description

Intervention group: Patients in this group use Lactocar brand Synbiotic in the form of 250 capsules containing 7 probiotic strains. Two capsules are consumed every day after lunch for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group use placebo for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Majid Aghadavood Marnani

Street address

Soffeh Blvd

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

Web page address

<http://alzahra.mui.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoy Javanmard

Street address

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Building No. 4, Vice Chancellor for Research and Technology

City

Esfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Majid Aghadavood Marnani

Position

Gastroenterology Fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Soffeh Blvd, Alzahra Hospital

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Majid.aghadavood@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Masha Khodadoostan Shahraki

Position

Gastroenterologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Soffeh Blvd, Alzahra Hospital

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

mkhodadoostan@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Majid Aghadavood Marnani

Position

Gastroentrology Fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Soffeh Blvd, Alzahra Hospital

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Majid.aghadavood@gmail.com

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

Information about the main outcome is shared.

When the data will become available and for how long

The start of the information access period is after the results are published.

To whom data/document is available

Researchers working in academic institutions and artisans can access information.

Under which criteria data/document could be used

The use of information in scientific articles is unrestricted.

From where data/document is obtainable

After the article is published, the information is available through reputable scientific sites.

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

After the article is published, the information is available through reputable scientific sites.

Comments