

# 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

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##### Postal code

8174675731

##### Phone

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##### 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

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**Email**

mkhodadoostan@yahoo.com

**Email**

Majid.ghadavood@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****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

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