

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Evaluating the effectiveness of adding probiotic supplements to standard treatment in the treatment process of pregnant women with COVID-19: a double-blind randomized clinical trial

Protocol summary

Study aim

Determining the effectiveness of adding probiotic supplements to standard treatment in the treatment process of pregnant women with COVID-19

Design

A clinical trial with control group, parallel groups, double-blind, randomized, phase3 will be performed on 80 patients. Randomization will be generated using a random generator program.

Settings and conduct

In this study, pregnant women with COVID19 admitted to Hospital are randomly assigned to two groups using a randomized 4block method. Random sequences are placed in closed envelopes in the "corona section". The patient and the outcome assessor do not know the nature of the codes (double-blind study).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with COVID-19 hospitalization in Hospital; positive PCR; Hospitalization on the day of admission; Onset of Covid symptoms up to 5 days before admission to the study; Gestational age > 12 weeks; Age ≥ 16 years; fever; respiratory rate ≥ 24/minute or oxygen saturation < 93% or Pa2/Fi2; Completion of informed consent form
Exclusion criteria: any obstetric problems, placental abruption; underlying diseases; chronic diseases and gastrointestinal disorders; History of receiving a probiotic supplement in the one week prior to enrollment

Intervention groups

The intervention group will receive Lactofem synbiotic capsules and the control group will receive placebo capsules 2 per day for at least 7 days (and until hospitalization). The course of the disease will be monitored by examining the clinical symptoms and blood tests.

Main outcome variables

Duration to the improvement of clinical and paraclinical

symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080826001096N8**

Registration date: **2022-01-02, 1400/10/12**

Registration timing: **prospective**

Last update: **2022-01-02, 1400/10/12**

Update count: **0**

Registration date

2022-01-02, 1400/10/12

Registrant information

Name

Seyede Hajar Sharami

Name of organization / entity

Guilan University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effectiveness of adding probiotic supplements to standard treatment in the treatment process of pregnant women with COVID-19: a double-blind randomized clinical trial

Public title
probiotic supplements in the treatment of pregnant women with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with mild / moderate COVID-19 hospitalization in Al-Zahra Hospital in Rasht Diagnosis based on a positive PCR or antigen test results Hospitalization on the day of admission Onset of Covid symptoms up to 5 days before admission to the study Gestational age > 12 weeks Age ≥ 16 years fever (oral temperature ≥ 37.2 ° C) Having at least one of the criteria of respiratory rate ≥ 24 per minute or oxygen saturation < 93 (without oxygen) Pa2 / Fi2 Completion of informed consent form
Exclusion criteria:
Existence of any obstetric problems such as premature rupture of the amniotic membrane, placental abruption History of receiving probiotic supplement for up to one week before enrollment Presence of underlying diseases and gastrointestinal disorders such as IBD Presence chronic diseases under treatment (such as asthma and allergies, heart failure) and acquired or congenital immunodeficiencies

Age
From 16 years old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random sequences will be generated using a random generator program. Based on the random block method and considering the quadruple blocks, a table with 20 rows (blocks) and each block with 4 sections (each section including A and B) will be produced for 80 pregnant women with COVID-19. After generating the list, each person will be assigned a unique code and the person will be identified with this code during the study. After all the numbers are placed in the blocks, the people who had the number in house A will receive the package with the code A and the people

who had the number in the house B will receive the package with the code B. Allocation Concealment will be done using sealed envelopes (SNOSE).

Blinding (investigator's opinion)

Double blinded

Blinding description

The double-blind clinical trial study will be performed using sealed envelopes (SNOSE). Based on the sample size of the research, several aluminum envelopes will be prepared and each of the random sequences created on a registered card and the cards will be placed in the envelopes respectively. In order to maintain a random sequence, the envelopes will be numbered in the same way on the outer surface. Finally, the envelope lid is glued and placed in a box, respectively. At the beginning of the intervention, the envelopes are opened in order and the assigned group of the participant is revealed. During the patient's hospital stay, due to the cold chain in Lactofem synbiotics, the package containing each patient's medication is stored in the Corona's refrigerator. The study was double-blind so that patients and outcome assessors were unaware of the status of the two study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

committee of Guilan University of Medical Sciences

Street address

P.O.Box: 4144654839, Reproductive Health Research Center, Al-zahra Hospital, Guilan University of Medical Sciences, Namjoo Street, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4144654839

Approval date

2021-11-24, 1400/09/03

Ethics committee reference number

IR.GUMS.REC.1400.406

Health conditions studied

1

Description of health condition studied

Coronavirus disease in pregnancy

ICD-10 code

O98.5

ICD-10 code description

Other viral diseases complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Duration from the start of the study until the improvement of clinical symptoms

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

Clinical examination (using patient record)

2

Description

Duration from the start of the study until the improvement of paraclinical symptoms

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

using patient record

Secondary outcomes

1

Description

Blood Oxygen Saturation Percentage (SPO2)

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

Pulse oximeter device

2

Description

Body temperature

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

Thermometer

3

Description

Pulse rate

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

Clinical evaluation

4

Description

Respiratory rate

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

Clinical evaluation

5

Description

Radiological changes

Timepoint

The day of discharge from the corona ward or earlier at the discretion of the research team

Method of measurement

Percentage of lung involvement in plain or CT scan of the chest

6

Description

Cough

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

Clinical evaluation by a specialist physician member of the research team

7

Description

Duration of hospitalization

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

Patients' records

8

Description

Blood pressure

Timepoint

The first day of study and the day of discharge from the "corona ward"

Method of measurement

Patients' records

9

Description

Serious side effects

Timepoint

At any time from the start of the study until the day of discharge from the corona

Method of measurement

Clinical evaluation

10

Description

Mortality

Timepoint

At any time, based on the Patients' records

Method of measurement

Number, based on hospital records

Intervention groups

1

Description

The intervention group (Probiotics+standard care treatment) will receive Lactofem synbiotic capsules (prepared by Zist-takhmir Company) twice daily after meals for at least 7 days until hospitalization. Each Lactofem capsule contains 500 mg of 4 strains of probiotic lactobacilli including Lactobacillus acidophilus, Lactobacillus plantarum, Lactobacillus fermentum, Lactobacillus gasseri and 38.5 mg of prebiotic substances including fructooligosaccharides. Probiotics are safe to take during pregnancy, and some pregnant women are usually prescribed 1-2 capsules daily to relieve constipation, prevent gestational diabetes, and reduce the risk of allergies in infants. The patient is visited by an infectious disease specialist (one of the project researchers). The course of the disease will be monitored by the research team by reviewing and comparing clinical symptoms and test results (Includes PCR and blood tests including CRP, CBC- diff, WBC, Platelet, lymph, ESR, CPK LDH) during the time of hospitalization in the corona ward.

Category

Treatment - Drugs

2

Description

Control group: (placebo+standard care treatment) will receive two placebo capsules (prepared by Zist-takhmir company) daily after meals for at least 7 days until hospitalization. Placebo is quite similar to a probiotic supplement in shape, color, odor, size and packaging, even the fillers or excipients available. The only difference is the absence of Lactobacillus and fructooligosaccharide strains in placebo. In both groups, the patient's routine management is entirely the responsibility of the medical staff. Patients are also provided with a telephone number to ask the researcher any questions about the supplement or study or any possible side effects.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Dr.Seyedeh Hajar Sharami

Street address

Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Naghipour

Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, Shahid Siadati St., Namjoo Ave., Rasht, Guilan, IRAN

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Dr. Seyedeh Hajar sharami

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Seyedeh Hajar sharami

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available