Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 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 withCOVID-19 hospitalization in Hospital; positive PCR; Hospitalization on the day of admission; Onset of Covid symptoms up to5 days before admission to the study; Gestational age>12 weeks; Age≥16years; fever; respiratory rate≥24/ minute or oxygen saturation< 93or 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 2per 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

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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

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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 fementum, Lactobacillus gasseri and 38.5 mg of prebiotic substances including fructoo oligosaccharides. 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 fructo oligosaccharide 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
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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 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