Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of probiotic use on control of sign and symptoms of admitted patients with covid-19

Protocol summary

Study aim
Evaluation of the effect of using probiotic products to control the symptoms of hospitalized patients with definite diagnosis of COVID-19

Design
Phase 3 trial, Randomized trial, with block randomization on 60 covid-19 patients, in two groups control and intervention, follow for 14 days.

Settings and conduct
Firoozabadi hospital, after infectious disease specialist visit and definite diagnosis of covid19, with block randomization, divided two groups, intervention and control then prebiotic will take to intervention patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: definite Covid19 patients; individual satisfaction. Exclusion criteria: pregnancy and breastfeeding; ICU admission; using herbal remedies; chemotherapy.

Intervention groups
Intervention group: standard therapy plus prebiotic. Control group: standard therapy.

Main outcome variables
Evaluation of Prebiotic on Covid19; fever; cough; respiratory rate; weakness; myalgia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161206031255N4**
Registration date: **2020-12-07, 1399/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-07, 1399/09/17**
Update count: **0**

Registration date
2020-12-07, 1399/09/17

Registrant information

Name
Elham Akhtari
Name of organization / entity
Iran university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-01-19, 1399/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of probiotic use on control of sign and symptoms of admitted patients with covid-19

Public title
Efficacy of prebiotic products on admitted patients with Covid-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent positive PCR or positive CT-scan
Exclusion criteria:
Patient's unwillingness to participate Dialysis patients ICU admitted or intubated patients Pregnancy orbreast

feeding use of steroid or immunosupressive medicatns use of the other herbal medications

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Initially, before starting the sampling, the row number from 1 to 60 is considered for all patients. Then, with the software SPSS, half of the numbers are randomly given to the patient group and the other half to the control. As soon as the patient enters the study, the row number is considered in the list in the order of entry. Grouping was done based on predetermined numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic's commitee of Beheshti university of Medical Sciences

Street address
Ethic's commitee, beside Taleghani hospital, Velenjak street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985711151

Approval date
2020-09-08, 1399/06/18

Ethics committee reference number
IR.SBMU.RETECH.REC.1399.562

Health conditions studied

1

Description of health condition studied
covid 19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
cough

Timepoint
Daily

Method of measurement
By question from the patient

2

Description
Breath rate

Timepoint
Four times in a day

Method of measurement
physical exam

3

Description
fever

Timepoint
Four times in a day

Method of measurement
physical exam

4

Description
weakness

Timepoint
daily

Method of measurement
examination

5

Description
myalgia

Timepoint
daily

Method of measurement
history

6

Description
C reactive protein

Timepoint
Daily

Method of measurement

Blood lab.

7

Description
Lymphocyte
Timepoint
Daily
Method of measurement
Blood lab.

8

Description
blood Oxygen saturation
Timepoint
four times in a day
Method of measurement
physical examination

9

Description
Diarrhea
Timepoint
daily
Method of measurement
Ask from patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients take standard medicine hydroxychlroquine and remdecevir. prebiotic powder 150 mg in the pack that 3 mg per dose for three times a day for 2 weeks.
Category
Treatment - Drugs

2

Description
Control group: hydroxychlroquin and remdecevir as standard treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozabadi hospital
Full name of responsible person
Roshanak Mokaberinejad
Street address
Firoozabadi hospital, Fadaeian eslam street, Rey town, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zerghi
Street address
Beside Taleghani hospital, Yemen street, Erabi stereet, Chamran highway, Tehran, Iran
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1985717443
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti Medical sciences University
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Roshanak Mokaberinejad
Position

Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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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