Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy and safety of "BioBoost" supplement on the incidence of COVID-19 symptoms of asymptomatic family members of COVID-19 patients: A Randomized cluster clinical trial, parallel, Phase 3, doubled blinded and placebo controlled

Protocol summary

Study aim
Use of probiotics to prevent the symptoms of Covid-19 in families where one of the members has Covid-19 disease

Design
This single-center study was in coordination with Keyvna Laboratory and Baqiyatallah University of Medical Sciences. After confirming the disease by PCR, obtaining informed consent from the patient and his family, and reviewing the inclusion/exclusion criteria to determine eligibility, the patients were considered as an index case. The study designed and implemented as a cluster.

Settings and conduct
The study was conducted using electronic forms and an electronic data collection management system. The process of clearing and locking data was managed online. Assessor, physician, and statistical analysis are blind. This single-center study was performed in coordination with Keyvan Laboratory in Tehran and Baqiyatallah University of Medical Sciences. .

Participants/Inclusion and exclusion criteria
• Inclusion criteria: 1- Confirmation of PCR infection in a family member 2- Informed written consent 3. Not participating in another clinical trial in the last three months 4- Do not use other supplements (containing vitamins, minerals, and probiotics) 5. Age between 18 to 63 years 6- No prognostic signs of Covid disease-19 two weeks before the study 7- No documented history of Covid-19 infection in healthy family members • Exclusion criteria: 1. Pregnant women/breastfeeding 2. Having a history of member transplants 3. Having a history of bowel surgery 4. Taking immunosuppressive drugs 5. Sensitivity to probiotic supplement ingredients Exclusion criteria 1. severe adverse event 2. reluctant 2. Reluctance to continue

Intervention groups
Group 1: Giving probiotics to patients' families Group 2: giving a placebo to patients' families

Main outcome variables
Estimating the incidence and severity of cough
Estimation of the incidence and severity of shortness of breath

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200318046812N3**
Registration date: **2021-01-12, 1399/10/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-12, 1399/10/23**
Update count: **0**

Registration date
2021-01-12, 1399/10/23

Registrant information

Name
Mostafa Ghanei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8860 0067

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mghaneister@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-20, 1399/09/30

Expected recruitment end date
2021-02-18, 1399/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy and safety of "BioBoost" supplement on the incidence of COVID-19 symptoms of asymptomatic family members of COVID-19 patients: A Randomized cluster clinical trial, parallel, Phase 3, doubled blinded and placebo controlled

Public title
Efficacy and safety of "BioBoost" supplement on the incidence of COVID-19 symptoms of asymptomatic family members of COVID-19 patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of infection by PCR in a family member Informed written consent Living in Tehran Number of family members between 2 and 5 Age between 18 to 63 years No prognostic signs of Covid-19 disease two weeks before enrollment
Exclusion criteria:
Not participating in another clinical trial in the last three months Do not use other supplements (containing vitamins, minerals, and probiotics) No documented history of Covid-19 infection in healthy family members Pregnancy / breastfeeding Drug sensitivity to the compounds in the intervention Temporary residence or immigration and consecutive relocation from Tehran Use similar supplements
Age
From **18 years** old to **63 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **500**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is designed as a cluster. The index patient was diagnosed with Covid-19 and the patient's family members were included in the study if they met the inclusion criteria and were assigned to one of the treatments. Random codes are generated by the permutation block method with variable block sizes to the estimated number of clusters. A dedicated code for each family member is tagged on the box along with a randomization code.
Blinding (investigator's opinion)
Double blinded
Blinding description
There is a special code on the box corresponding to the randomization list. In order to enter the patient and determine the relevant box, the project management is inquired. Therefore, the patient and the evaluator and statistical analyzer will only see the label on the probiotic.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Chamran Hospital Ethics Committee
Street address
Shahid Chamran Hospital, Sanaye St., Shahid Langari St., Nobniad Sq., Tehran
City
Tehran
Province
Tehran
Postal code
12345
Approval date
2020-12-14, 1399/09/24
Ethics committee reference number
IR.CHAMRANHOSPITAL.REC.1399.002

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
Ṡẻverity of cough
Timepoint
The variable in the drug and placebo groups can be recorded at the end of the first, second and fourth weeks
Method of measurement

Telephone followup

2

Description
Ṡeverity of shortness of breath
Timepoint
The variable in the drug and placebo groups can be recorded at the end of the first, second and fourth weeks
Method of measurement
Telephone followup

Secondary outcomes

1

Description
Preentation of fever, headache, .. as a Yes/ no
Timepoint
The variable in the drug and placebo groups can be recorded at the end of the first, second and fourth weeks
Method of measurement
Telephone follow-up

2

Description
Recording the severity of symptoms by comparing Likert from a score of 1 to 10
Timepoint
The variable in the drug and placebo groups can be recorded at the end of the first, second and fourth weeks
Method of measurement
Telephone follow-up

3

Description
The duration of symptoms and duration of hospitalization based on the date of onset and date of remission
Timepoint
The variable in the drug and placebo groups can be recorded at the end of the first, second and fourth weeks
Method of measurement
Telephone follow-up

Intervention groups

1

Description
''Intervention group:'' In this group, probiotics are given to the patients' families. Biomus supplement consists of 12 essential vitamins and minerals along with probiotics (a mixture of three native Iranian strains including Lactobacillus casei, L. rhamnosus and L. helveticus). All these items are prepared in one capsule to strengthen the immune system and digestive system against viral and bacterial diseases.Three capsules of medicine/placebo are delivered daily to the participants after receiving informed consent and the eligibility of the cluster at the initial visit. In follow-up visits, after receiving the previous drug pack/placebo, the new treatment is sent to the patient's family using a courier. The amount of medicine/placebo delivered is enough until the next visit.
Category
Prevention

2

Description
''Control group'': Placebo is given to patients three times a day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Keyvan Virology Specialty Laboratory (KVSL)
Full name of responsible person
Hossein Keyvani
Street address
Tehran Province, Tehran, District 7, Beheshti St number 498
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24321
Phone
+98 21 8810 4893
Email
contactus@keyvanlab.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mostafa Ghanei
Street address
aqiyatallah Hospital, Mollasadra Ave., Vanak Square ., Tehran
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mghaneister@gmail.com
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
20
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Hasan Saadat
Position
Professor
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Psychology
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Person responsible for updating data

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Email
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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Potential data such as information about the main outcome can be shared after the confidentiality of individual information
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of data and its analysis is allowed if be cited

From where data/document is obtainable

Dr Mostafa Ghanei; Chemical Injuries Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran.Email: mghaneister@gmail.com; Phone: +9821 88600067

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

The processes that must be followed by the applicant for these documents or data files will include a letter of request, a letter of request from the center or university of origin, acceptance of the destination university, and proof of eligibility to receive the information.

Comments