# Title : **Probiotic and Colchicine in COVID-19**

ClinicalTrials.gov Identifier: NCT05911022

**Sponsor:**

Ain Shams University

**Information provided by (Responsible Party):**

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**Study Description**

Brief Summary:

Probiotics and or Colchicine may be considered as an option of treatment since they have anti-viral effect anti-inflammatory and immunomodulatory effect. A total of 150 participants were were randomly assigned (1:1:1) to receive either the standard treatment protocol and colchicine or the standard treatment protocol and probiotics or the standard treatment protocol alone for two weeks. Participants followed up twice weekly by telephone.

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| **Condition or disease** | **Intervention/treatment** |
| **COVID-19** | Drug: Colchicine 0.5 MGDietary Supplement: Probiotic FormulaOther: Standard protocol |

Detailed Description:

Rational:

At the end of 2019, a novel coronavirus was identified as the causative of a cluster of pneumonia cases in Wuhan, China. resulting in an epidemic throughout China, followed by a global pandemic. In February 2020, the World Health Organization announced the disease COVID-19, which stands for coronavirus disease 2019.

Gut microbiota configuration was associated with COVID-19 disease severity, and altered gut microbiota persisted even after clearance of the virus, suggesting that the virus might inflict prolonged harm to human microbiome homoeostasis.

Probiotics as an intestinal microbe regulator, not only improve the ability of the GI microbiota to modulate immune activity, but also strengthen the body's immune system, inhibit allergic reactions and has a significant role especially in the anti-viral immunomodulation.

Colchicine is an anti-inflammatory medication commonly used for the treatment systemic auto inflammatory diseases such as familial Mediterranean fever and Behçet's disease. Its mechanism of action is through inhibition of neutrophil chemotaxis and activity in response to vascular injury .

Therefore, in patients with COVID-19, probiotics and or Colchicine, may be a therapeutic choice. However, there is still a lack of evidence-based studies to support this, so it is necessary to conduct further studies and provide evidence to clinicians.

Objectives:

To assess effectiveness of probiotic supplement (Lactobacillus Acidophilus) and Colchicine on symptoms, duration and progression of mild and moderate cases of COVID-19 infection.

Participants:

Participants with mild and moderate COVID-19 severity, aged 18 to 64 were included in the trial.

Sample size:

A total of 150 participants who satisfied the inclusion criteria had their data gathered between the beginning of July 2021 and the end of August 2022.

Randomization:

To distribute intervention or control codes, the investigator used sealed envelopes. Fifty participants was included in each group( 25 mild and 25 moderate cases).

Intervention:

Participants were randomly assigned (1:1:1) to receive either the standard treatment protocol and colchicine or the standard treatment protocol and probiotics or the standard treatment protocol alone or for two weeks.

Data collection:

each participants had the following procedures:

1. Sociodemographic information was gathered for the clinical history, including age, gender, marital status, place of residence, smoking history, etc.
2. Medical information included weight, current medications, symptoms (onset, course, and duration), and the presence of co-morbidities.
3. The temperature, heart rate, blood pressure, respiratory rate, and oxygen saturation are all measured during a thorough general examination.

participants who met the CDC's criteria for suspicion had radiographic and laboratory confirmation using the tests PCR-COVID-19, Complete Blood Count, CRP, Ferritin and D-Dimer, as well as High-resolution CT chest.

Follow up:

Participants followed up twice weekly by telephone for evaluating their symptoms, development of new symptoms, compliance on treatment, temperature measurement and psychological support.

Data Analysis:

Analysis of data of the participants is divided into three groups, the first patients received Colchicine, the second patients received probiotics and the third control group.

Descriptive statistics including quantitative data presented as mean and SD and Qualitative data presented as number and percentage.

Analytical statistics including bivariate analyses using the chi-square test for categorical variables. For comparison of Lab investigation before and during the treatment Mc Nemar test used for qualitative binary variables and Marginal Homogeneity test used for nominal variables.

**Study Design**

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| Study Type  : | Interventional  (Clinical Trial) |
| Actual Enrollment  : | 150 participants |
| Allocation: | Randomized |
| Intervention Model: | Parallel Assignment |
| Intervention Model Description: | Three-arm randomized controlled interventional study |
| Masking: | Single (Participant) |
| Masking Description: | The researcher will use sealed envelopes containing code for intervention or control. |
| Primary Purpose: | Treatment |

**Groups and Cohorts**

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| **Group/Cohort** | **Intervention/treatment** |
| Active Comparator: Group A (Colchicine group)  consisted of COVID-19 participants with mild to moderate disease who received the recommended course of care in accordance with the protocol established by the Egyptian Supreme Council of University Hospitals, as well as Colchicine tablets (0.5 mg) three times per day for three days and subsequently twice per day for four days | Drug: Colchicine 0.5 MG  three times per day for three days and subsequently twice per day for four days |
| Active Comparator: Group B (Probiotic group)  consisted of COVID-19 participants with mild and moderate COVID-19 severity got probiotics in the form of oral sachets once daily for two weeks in addition to protocol prescribed by the Egyptian Supreme Council of University Hospitals. | Dietary Supplement: Probiotic Formula  oral sachets once daily for two weeks |
| Placebo Comparator: Group C (Control group)  consisted of COVID-19 participants with mild and moderate severity who received the recommended course of care in accordance with the protocol established by the Egyptian Supreme Council of University Hospitals (Vitamin C 500 mg twice daily, Vitamin D3 2000-4000 IU/day, Zinc 75 mg once daily for two weeks, and necessary protocol of management based on case assessment and severity). | Other: Standard protocol  the Egyptian Supreme Council of University Hospitals (Vitamin C 500 mg twice daily, Vitamin D3 2000-4000 IU/day, Zinc 75 mg once daily for two weeks |

**Outcome Measures**

Primary Outcome Measures  :

1. symptoms improvement [ Time Frame: two weeks ]

Discharge from isolation after 10 days after symptom onset, plus at least 3 additional days without symptoms (including without fever and without respiratory symptoms) According to WHO recommendations published on 27 May 2020.

Secondary Outcome Measures  :

1. Development of new symptoms. [ Time Frame: two weeks ]

new symptoms like dyspnea, diarrhea or other symptoms reported by the participants

1. Need for oxygen supplementation. [ Time Frame: two weeks ]

If oxygen saturation below 94%

**Eligibility Criteria**

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| Ages Eligible for Study: | 18 Years to 64 Years   (Adult) |
| Sexes Eligible for Study: | All |
| Accepts Healthy Volunteers: | No |
| Ages Eligible for Study: | 18 Years to 64 Years   (Adult) |

**Criteria**

Inclusion Criteria:

* Participants aged (18-60) years with confirmed criteria of COVID-19 infection. Mild cases: Participants have mild symptoms such as anosmia, loss of taste, fever or respiratory tract symptoms, gastrointestinal symptoms, etc. and free chest imaging. Moderate Cases: Participants have symptoms such as fever, respiratory tract symptoms, gastrointestinal symptoms, etc. and pneumonia manifestations can be seen in chest imaging

Exclusion Criteria:

* Age below 18 years or above 60 years.
* Pregnancy, lactation.
* Any co-morbidities e.g. (DM, hypertension, Asthma)
* Participants receiving immunosuppressive or chemotherapy drugs.
* Active malignancy
* Severe confirmed cases, fulfilling any of the following criteria:
  1. Respiratory rate more than 30/min.
  2. Blood oxygen saturation of less than 93%.
  3. Lung infiltrates >50% of the lung fields or rapid progression within 24-48 hours.
  4. Participants need respiratory support e.g. high flow oxygen, non-invasive or invasive mechanical ventilation.
* Critical cases defined as: occurrence of respiratory failure requiring mechanical ventilation; Presence of shock; other organ failure that requires monitoring and treatment in the ICU

**Locations**

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| **Egypt** | |
| Ain Shams University |  |
| Cairo, Egypt, 190519 | |

**Sponsors and Collaborators**

Ain Shams University