# Should Colchicine be used in the treatment of COVID-19?

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## KEY FINDINGS

There is currently insufficient evidence on the use of colchicine in the treatment of COVID-19 patients, but there are 4 ongoing trials awaiting completion this 2020.

- **Colchicine is an anti-inflammatory agent currently being used for inflammatory conditions such as gout, familial Mediterranean fever, Behcet's syndrome and pericarditis.**
- **Its powerful anti-inflammatory properties may have the potential to prevent the development of COVID-19 complications.**
- **There are currently no evidence for its use on COVID-19 patients, but there are 4 ongoing studies that may be released from the period of May 2020 to September 2020.**
- **Common adverse events include gastrointestinal effects such as diarrhea but does not exhibit serious and life-threatening adverse events.**
- **There is no mention of colchicine in the WHO Interim Guidance, US CDC Clinical Interim Guidelines and Chinese Clinical Guidance for COVID-19 management.**

## RESULTS

There are currently no studies or clinical trials specifically answering the question on whether colchicine can be used for the treatment of COVID-19 patients. However, four (4) ongoing trials are listed in *ClinicalTrials.gov* to specifically answer that question, namely GRECCO-19, Colchicine Efficacy in COVID-19 Pneumonia, COLCOVID and COLCORONA. The 2 latter studies originated from Canada while GRECCO-19 and Colchicine Efficacy in COVID-19 Pneumonia are from Greece and Italy, respectively. Only the COLCORONA study has started recruitment at this time.

## CONCLUSION

As of this writing, there is insufficient evidence for the use of colchicine for COVID-19 patients, but there are ongoing trials that will release their results within the year. This report will be updated as soon as the result of a completed study comes out.

## Declaration of Conflict of Interest

No conflict of interest

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## Table 1. Characteristics of Ongoing Clinical Trials

| No. | Clinical Trial ID / Title | Status | Start & estimated primary completion date | Study design | Country | Population | Intervention Group(s) | Comparison Group(s) | Outcomes |
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| 1 | The Greek Study in the Effects of Colchicine in Covid-19 (GRECCO-19) | Not yet recruiting | 06 April to 30 Sep 2020 | RCT<br>Open label | Greece | Adults with laboratory confirmed SARS-CoV-2 infection AND body temperature >37.5 degrees centigrade AND at least two of: (1) sustained coughing, (2) sustained throat pain, (3) anosmia and/or ageusia, (4) fatigue/tiredness, (5) PaO2<95 mmHg. | Low-dose colchicine 0.5mg BID, on top of standard treatment | Standard treatment, including all medications recommended by the National Public Health Organization | CRP increase to 3 x upper limit of normal (Time Frame: 3 weeks)<br>Time to increase in C-reactive protein to 3 times the ULN<br><br>Clinical deterioration in the semiquantitative ordinal scale suggested by the WHO R&D committee (Time Frame: 3 weeks)<br>Time to clinical deterioration (2 levels in the WHO R&D Blueprint scale) |
| 2 | The ECLA PHRI COLCOVID Trial (COLCOVID) | Not yet recruiting | March to 30 May 2020 | RCT<br>Open label | Canada | Consented adults (age ≥18 years)<br>COVID-19 suspicious and admitted to hospital or already in hospital and fever (with or without at the time of randomization) and<br>SARS (severe acute respiratory syndrome)<br>shortness of breath - (dyspnea) or image of typical or atypical pneumonia or oxygen desaturation (SpO2 ≤ 93) | Local standard care plus colchicine with specific dosage schedule | Local standard of care for COVID-19 SARS moderate / high-risk patients | Primary Outcome Measures:<br>All-cause mortality<br>(Time Frame: During hospitalization or until death, whichever comes first, assessed up to 30 days)<br><br>Secondary Outcome Measures:<br>Composite of intubation for mechanical ventilation or death.<br>(Time Frame: During hospitalization or until death, whichever comes first, assessed up to 30 days)<br>Number of participants who require intubation for mechanical ventilation or die |
| 3 | Colchicine Efficacy in COVID-19 Pneumonia | Not yet recruiting | 01 April to 30 May 2020 | RCT<br>Open label | Italy | Adults;<br>According to the risk stratification criteria of the Emilia-Romagna Region, Italy (accessed on March 24th, 2020 http://www...), eligible patients will belong to the Scenario 2, and 3a (slightly modified) as follows:<br><br>Scenario 2 Positive nasopharyngeal swab for COVID-19, asymptomatic or paucisymptomatic, aged ≥70 years and/or with clinical risk factors for poor outcome (clinically relevant chronic lung disease, diabetes and/or heart disease) or - symptomatic with respiratory or systemic symptoms, however clinically stable (MEWS<3) with CT imaging showing viral pneumonia and positive or pending pharyngo-nasal swab for COVID-19: | Colchicine 1mg (or 0.5mg in CKD)/day plus standard care for COVID-19 pneumonia | Standard of care for COVID-19 pneumonia | Primary Outcome Measures:<br>Clinical improvement<br>(Time Frame: Day 28)<br>- Time to clinical improvement: defined as time from randomization to an improvement of two points from the status at randomization on a seven-category ordinary scale<br>Hospital discharge (Time Frame: Day 28)<br>- Live discharge from the hospital (whatever comes first)<br><br>Secondary Outcome Measures:<br>Death (Time Frame: Day 28)<br>Clinical status (Time Frame: Day 4, 7, Day 14, Day 21)<br>- 7-category ordinal scale |

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| | | | | | | Temperature 38°C and/or intensive cough, Respiratory rate < 25 /min, oxygen saturation (pulse oximetry) >95%<br>Scenario 3 A<br>Positive swab for COVID-19<br>- with respiratory and/or systemic symptoms and initial mild respiratory failure e with objective signs of lung involvement; the patient is in stable conditions (MEWS < 3)<br>Temperature>38°C and or intensive cough, Respiratory rate ≥25 /min, or oxygen saturation 94- 95% in room air | | | Mechanical ventilation<br>(Time Frame: Day 28)<br>Hospitalization (Time Frame: Day 28)<br>Time from death (Time Frame: Day 28)<br>Negativization COVID 19 (Time Frame: Day 21)<br>- negativization of two consecutive pharyngo-nasal swab 24-72 hrs apart<br>Fever (Time Frame: Day 1,4,7,14,21,28)<br>- Time to remission of fever in patients with T>37.5°C at enrollment |
| 4 | Colchicine Coronavirus SARS-CoV2 Trial (COLCORONA) | Recruiting | 23 March to September 2020 | RCT<br>Single blind (participant) | Canada | Adults 40 years and older;<br>Received a diagnosis of COVID-19 infection within the last 24 hours;<br>Outpatient setting (not hospitalized);<br>Must possess at least on of the following high-risk criteria:<br>70 years or more of age, diabetes mellitus, uncontrolled hypertension (systolic blood pressure ≥150 mm Hg), known respiratory disease (including asthma or chronic obstructive pulmonary disease), known heart failure, known coronary disease, fever of ≥38.4°C within the last 48 hours, dyspnea at the time of presentation, bicytopenia, pancytopenia, or the combination of high neutrophil count and low lymphocyte count;<br>Female patient is either not of childbearing potential, defined as postmenopausal for at least 1 year or surgically sterile, or is of childbearing potential and practicing at least one method of contraception and preferably two complementary forms of contraception including a barrier method (e.g. male or female condoms, spermicides, sponges, foams, jellies, diaphragm, intrauterine device (IUD)) throughout the study and for 30 days after study completion;<br>Patient must be able and willing to comply with the requirements of this study protocol. | Colchicine 0.5mg twice daily for first 3 days and then once daily for the last 27 days | Placebo twice daily for the first 3 days and then once daily for the last 27 days | <u>Primary Outcome Measures:</u><br>Number of participants who die or require hospitalization due to COVID-19 infection (Time Frame: 30 days post randomization)<br>The primary endpoint will be the composite of death or the need for hospitalization due to COVID-19 infection in the first 30 days after randomization.<br><br><u>Secondary Outcome Measures:</u><br>Number of participants who die (Time Frame: 30 days post randomization)<br>The secondary endpoint is the occurrence of death in the 30 days following randomization.<br>Number of participants requiring hospitalization due to COVID-19 infection (Time Frame: 30 days post randomization)<br>The secondary endpoint is the need for hospitalization due to COVID-19 infection in the 30 days following randomization.<br>Number of participants requiring mechanical ventilation<br>(Time Frame: 30 days post randomization)<br>The secondary endpoint is the need for mechanical ventilation in the 30 days following randomization. |