

## Could colchicine be effective for treatment of COVID-19?

### Background on Colchicine

FDA-approved uses <sup>1,2</sup>	<ul style="list-style-type: none"> <li>• Treatment and prevention of gout flares in persons aged &gt;16 years</li> <li>• Treatment of FMF in adults and children aged ≥4 years</li> </ul>
Dosage and administration <sup>1,2</sup>	
Gout treatment	1.2 mg at first sign of flare followed by 0.6 mg 1 hour later
Gout prophylaxis	0.6 mg once or twice daily; maximum 1.2 mg daily
FMF	Dose according to age, in 1 or 2 divided doses per day <ul style="list-style-type: none"> <li>• Age &gt;12 years: 1.2 to 2.4 mg</li> <li>• Age 6 to 12 years: 0.9 to 1.8 mg</li> <li>• Age 4 to 6 years: 0.3 to 1.8 mg</li> </ul>
How supplied <sup>2</sup>	Oral capsules or tablets (0.6 mg) and oral solution 0.6 mg/5 mL

FDA=Food and Drug Administration; FMF=familial Mediterranean fever

- Colchicine is an anti-inflammatory drug.<sup>1,2</sup> In terms of its mechanism, the drug is known to:
  - Interfere with migration of neutrophils to sites of inflammation induced by accumulation of monosodium urate crystals in synovial fluid, and
  - Block the inflammasome complex in neutrophils and monocytes mediating interleukin-1beta activation.

### Pertinent Literature

As of March 30, 2020:

- There are no published studies evaluating the efficacy of colchicine in patients with COVID-19.
- A search of [clinicaltrials.gov](https://clinicaltrials.gov) revealed 3 registered studies-in-progress:<sup>3</sup>

Characteristics	NCT04326790, aka GRECCO-19	NCT04322682, aka COLCORONA	NCT04322565
Sponsor	National and Kapodistrian University of Athens	Montreal Heart Institute	Lucio Manenti, Universitaria di Parma, Italy
Study design	Phase 4, R, OL trial	Phase 3, MC, R, DB, PC trial	Phase 2, R, OL trial
Inclusion criteria	Adults aged ≥18 years with COVID-19 and oxygen saturation <94 mmHg	~6000 adults aged ≥40 years with diagnosis of COVID-19 in last 24 hours, not hospitalized, and at high risk*	Adults aged 18-85 years with COVID-19 and either 1) asymptomatic with risk factors for poor outcome,** or 2) with respiratory and/or systemic symptoms but stable
Interventions	Colchicine 0.5 mg PO BID or standard treatment	Colchicine 0.5 mg PO, BID for 3 days, then daily for 27 days, or placebo	Colchicine 1 mg PO daily (0.5 mg daily in CKD) + standard of care, or standard of care alone
Primary endpoint	Time to increase in C-reactive protein to 3x ULN	Death or hospitalization in 30 days	Clinical improvement within 28 days

BID=twice daily; CKD=chronic kidney disease; COLCORONA=Colchicine Coronavirus SARS-CoV2 trial; DB=double-blind; GRECCO=The Greek study in the Effects of Colchicine in COVID-19; MC=multicenter; NCT number=national clinical trial identifier; OL=open-label; PC=placebo-controlled, PO=by mouth; R=randomized; ULN=upper limit of normal.

\*At least 1 of following: age ≥70 years, diabetes mellitus, systolic blood pressure ≥150 mmHg, respiratory disease (e.g., asthma), heart failure, coronary disease, fever ≥38.4°C in last 48 hours, dyspnea, pancytopenia, or high neutrophil count and low lymphocyte count.

\*\*Age ≥70 years and/or chronic lung disease, diabetes, and/or heart disease.

### Recommendations from Governmental Agencies

As of March 30, 2020, the Centers for Disease Control and Prevention does not address colchicine as a potential therapeutic option for patients with COVID-19.<sup>4</sup> No recommendations on colchicine use were found from the Food and Drug Administration, World Health Organization, and the European Medicines Agency.

### Conclusion

As of March 30, 2020, there is not enough information to determine whether colchicine could be effective for treatment of COVID-19.