Results of the COLCORONA study published in The Lancet Respiratory Medicine

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Colchicine could be considered as a treatment for non-hospitalized patients diagnosed with COVID-19 by PCR test and at risk of complications

The Montreal Heart Institute (MHI) announces that the COLCORONA study results are published today in The Lancet Respiratory Medicine. The article, which is entitled Colchicine for community-treated patients with COVID-19 (COLCORONA): a phase 3, randomised, double-blinded, adaptive, placebo-controlled, multicentre trial, concludes that, given the lack of oral therapies available to prevent COVID-19 complications among non-hospitalized patients and the observed benefit of colchicine in patients with a PCR-confirmed diagnosis of COVID-19, this anti-inflammatory drug could be considered as a treatment for those at risk of complications.

“Given the current pandemic, while awaiting collective immunity through vaccination around the world, the need for treatments to prevent COVID-19 complications among patients who contract the disease remains”, said Dr. Jean-Claude Tardif, Director of the MHI Research Centre, Professor at the Faculty of Medicine of the Université de Montréal and Principal Investigator of COLCORONA. “Our study showed that colchicine could be used to reduce the risk of complications for some patients with COVID-19.”

Colchicine is an inexpensive and readily available anti-inflammatory drug. Orally administered, it is currently prescribed to treat gout, Familial Mediterranean Fever and pericarditis. The COLCORONA study assessed colchicine’s potential to reduce the risk of COVID-19-related complications in outpatients over 40 years of age with at least one risk factor for disease progression.

The study’s primary efficacy endpoint was the composite of death or hospitalization in patients with COVID-19. Of the 4,488 patients enrolled, including those without a PCR-confirmed diagnosis, the primary endpoint occurred in 4.7% of patients in the colchicine group and 5.8% of those in the placebo group, a non-statistically significant result. For the 4,159 patients with a PCR-based diagnosis of COVID-19, the primary endpoint occurred in 4.6% of patients in the colchicine group and 6.0% of patients in the placebo group, a statistically significant result. Serious adverse events were reported in 4.9% of patients in the colchicine group and 6.3% of those in the placebo group. Notwithstanding these results, it is recommended that studies such as this one be replicated in non-hospitalized patients with a PCR-confirmed diagnosis of COVID-19. Full study results are available here: http://www.thelancet.com/journals/lancet/article/PIIS2213-2600(21)00222-8/fulltext.

“The COLCORONA study expands on our knowledge of the role of oral, cheap and widely available repurposed drugs such as colchicine to treat people early on to prevent serious complications of COVID-19 and can help practitioners and their patients make informed treatment decisions,” said Yves Rosenberg, M.D., M.P.H., chief of the Atherothrombosis and Coronary Artery Disease Branch at the National Heart, Lung, and Blood Institute, part of the United States National Institutes of Health.

COLCORONA (NCT04322682) is a randomized, double-blinded, placebo-controlled, home-based clinical trial. It was conducted in Canada, the United States, Europe, South America, and South Africa. The study included 4,488 non-hospitalized patients over 40 years of age with COVID-19 at the time of inclusion, with at least one identified risk factor for COVID-19 complications (e.g., diabetes, hypertension, known respiratory
disease, obesity). Patients were randomized to receive colchicine (0.5 mg twice daily for three days and once daily after) or placebo for 30 days.

The Montreal Health Innovation Coordinating Centre (MHICC) at the MHI coordinated COLCORONA, which was funded by the Quebec government, the National Heart, Lung, and Blood Institute of the U.S. National Institutes of Health (NIH), Montreal philanthropist Sophie Desmarais, and the COVID-19 Therapeutics Accelerator, an initiative launched by the Bill & Melinda Gates Foundation, Wellcome and Mastercard. Montreal-based CGI, Dacima and Pharmascience were also collaborators in the study.

**About the Montreal Heart Institute**
Founded in 1954, the Montreal Heart Institute constantly aims for the highest standards of excellence in the cardiovascular field through its leadership in clinical and basic research, ultra-specialized care, professional training, and prevention. It houses the largest cardiology research center in Canada, the largest cardiovascular prevention center in the country, and the largest cardiovascular genetics center in Canada. The Institute is affiliated with the Université de Montréal and has more than 2,000 employees, including 245 doctors and more than 85 researchers. [icm-mhi.org](http://icm-mhi.org)

**About the Montreal Health Innovations Coordinating Center (MHICC)**
The Montreal Health Innovations Coordinating Center (MHICC) is a leading academic clinical research organization and an integral part of the Montreal Heart Institute (MHI). The MHICC possesses an established network of collaborators in over 4,500 clinical sites in more than 35 countries. It has specific expertise in precision medicine, low-cost high-quality clinical trials, and drug repurposing. [mhicc.org](http://mhicc.org)

**About Pharmascience**
Founded in 1983, Pharmascience Inc. is the largest pharmaceutical employer in Quebec. With its head office located in Montreal and its 1,500 employees, Pharmascience Inc. is a private pharmaceutical company with deep roots in Canada, and whose global reach spans across more than 60 countries. Ranked 47th among the top 100 Canadian investors in Research and Development (R&D), thanks to $49.5 million investment in 2018, Pharmascience Inc. is one of the largest manufacturer of generic drugs in the country. [pharmascience.com](http://pharmascience.com)

**About CGI**
Founded in 1976, CGI is one of the world’s largest information technology (IT) and management consulting firms. From hundreds of locations around the world, CGI offers a complete portfolio of services and solutions: strategic IT and management consulting services, systems integration services, intellectual property solutions as well as IT and business process management services in delegated mode. [cgi.com/canada](http://cgi.com/canada)

**About Dacima**
Founded in 2006, Dacima Software Inc. is a leading innovator in Electronic Data Capture (EDC) software for clinical research. Dacima’s EDC software, Dacima Clinical Suite, is a fully feature EDC software application with integrated modules for patient randomization (IWRS), supply management, ePRO, eDiary, medical coding and eConsent. Dacima’s flexible and highly configurable EDC platforms allow for the design of all types of study designs including clinical trials, patient registries, observational studies and web surveys through an intuitive user-friendly web interface. [dacimasoftware.com](http://dacimasoftware.com)

**About the COVID-19 Therapeutics Accelerator**
The Therapeutics Accelerator is an initiative launched by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard with support from public and philanthropic donors to speed up the response to the COVID-19
pandemic by identifying, assessing, developing, and scaling up treatments. Its partners are committed to equitable access, including making products available and affordable in low-resource settings. www.therapeuticsaccelerator.org