

Can inhaled corticosteroids alleviate early symptoms of COVID-19?

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Despite high hopes, a new pan-Canadian study published today in *The BMJ* suggests that ciclesonide—an inhaled and nasal steroid drug commonly used for asthma and rhinitis—won't be the treatment to

change the course of the pandemic. The results of this first placebo controlled trial of inhaled steroids for COVID-19, led by a team of researchers at the Research Institute of the McGill University Health Centre (RI-MUHC) in Montreal, in collaboration with scientists from Sunnybrook Health Sciences Centre in Toronto, Vancouver Coastal Health Research Institute and the University of British Columbia in Vancouver, show that inhaled corticosteroids are no better than placebo at helping young healthy people with COVID-19 and respiratory symptoms feel better sooner.

Early on in the pandemic, Dr. Nicole Ezer, the first and lead author of the study, read studies that showed that treatment with ciclesonide—a safe, inexpensive and widely available drug—could decrease viral replication of SARS-Cov2 in mouse models of COVID-19. With the support of the McGill Interdisciplinary Initiative in Infection and Immunity (MI4) and the MUHC Foundation, she assembled a team of researchers that designed a randomized, double-blind, placebo-controlled trial of inhaled ciclesonide to evaluate the resolution of symptoms in adults with COVID-19 presenting with respiratory symptoms.

"Based on my experience treating asthma, I thought it made sense to see if it would decrease the lung inflammation in [patients](#) with COVID-19 early in the disease, as lung disease has an important impact for patients and is a major effect of the virus," says Dr. Ezer, who is a lung specialist and a researcher in the Translational Research in Respiratory Diseases Program at the RI-MUHC. "In addition, we felt it was important to study a drug for COVID-19 that has a very good safety profile and could be used in high, middle and low-income countries safely to reduce respiratory symptoms. Access to affordable medications is very important to decrease disparities in health outcomes across the world."

The importance of placebo control

A total of 215 symptomatic adults were recruited between September 15, 2020, and June 8, 2021, and randomly assigned either inhaled and intranasal ciclesonide or inhaled and intranasal placebo for 14 days. They were asked to complete a survey online on the day of enrollment and on six other occasions until day 14. A follow-up survey was sent on day 29 to capture longer term outcomes.

Based on the assumption that treatment would be most effective if given early in the disease process, participants were recruited within five days of a positive PCR test result for SARS-CoV-2 and symptom onset and received the treatment at home by commercial courier. No vaccinated participants were included in the trial.

The study showed no significant difference between the intervention and control group. After seven days of treatment, 40 percent (42/105) of participants who took the study drug had no more fever and respiratory symptoms, vs. 35 percent (34/98) of those who took the placebo. At day 14, these figures amounted to 66 percent (69/105) in the ciclesonide group compared with 58 percent (57/98) in the placebo group.

Those results are disappointing, especially since two recent open label studies had raised hopes in the scientific community that inhaled steroids could alleviate respiratory symptoms associated with COVID-19, and one study demonstrated efficacy of dexamethasone in admitted patients with COVID-19.

"The previously published studies had a major limitation: They were open label with no placebo. Other studies have shown that inhalers have a strong placebo effect," explains the senior author of the study, Dr. Emily McDonald, who is the Director of the MUHC Clinical Practice Assessment Unit and an associate professor of medicine at McGill University. "Here's a strong reminder that any study of a medication, in particular of inhalers, needs to be controlled with a placebo before we

rush to recommend them."

In spite of the CONTAIN study's results, researchers still believe in the potential inhaled steroids to treat COVID-19.

"It's still possible that inhaled steroids might be beneficial for older at risk populations," says Dr. Ezer, who is also an assistant professor of medicine at McGill University. "We need more research focused on older adults and people who are high-risk, but those studies must have a placebo arm to make sure they aren't coming to a false conclusion of benefit."

A novel approach and fruitful collaboration to overcome pandemic challenges

Thanks to an innovative platform developed at the RI-MUHC, enrollment in the study was contactless. Everything was completed online, from the consent form and proof of identity to the follow-up surveys. The study was able to enroll participants in three provinces quickly during the second and third waves by leveraging this novel platform.

"It is very novel to recruit patients who are at home, ship medications to their house and follow up by phone for clinical trials," says Dr. McDonald, who helped create this electronic platform to enable the conduct of clinical trials during the pandemic. "We demonstrated we can do this safely and efficiently across Canada."

With the participation of researchers at Sunnybrook Health Sciences Centre and the University of British Columbia, recruitment of participants was quickly extended to the provinces of Ontario and British Columbia.

"The CONTAIN study shows why it is so important to conduct rigorous, [placebo](#)-controlled studies to determine whether a treatment truly confers benefit," says Dr. Nick Daneman, clinician-scientist and infectious diseases specialist at Sunnybrook Health Sciences Centre.

"We have followed nearly 10,000 patients in our COVIDEO outpatient program since early 2020 and have avoided use of unproven therapies. Ciclesonide is a safe medication which had theoretic reasons why it might speed recovery from COVID, so we were excited to offer this treatment to our patients within the structure of the trial. In the end, it turns out that this treatment most likely does not impact the course of COVID."

"More research is needed to focus on treatments for outpatients who are in the beginning stages of COVID-19," says Dr. Sara Belga, clinical assistant professor in the Division of Infectious Diseases at the University of British Columbia and principal investigator of the CONTAIN study at the Vancouver Coastal Health Research Institute. "Our research team is committed to continue investigating medication that could speed up recovery of COVID-19 symptoms and to reduce additional strain on the health care system."

"Innovation comes from having the resources to support projects like CONTAIN," says Julie Quenneville, President and CEO of the MUHC Foundation. "While this study may not have produced the results researchers were hoping for, it is imperative to give our top-talent the time and funding they need to find answers to COVID-19 and other life-threatening conditions."

More information: Nicole Ezer et al, Inhaled and intranasal ciclesonide for the treatment of covid-19 in adult outpatients: CONTAIN phase II randomised controlled trial, *BMJ* (2021). [DOI: 10.1136/bmj-2021-068060](https://doi.org/10.1136/bmj-2021-068060)

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