CanTreatCOVID
Canadian Adaptive Platform Trial of Treatments for COVID in Community Settings

# Refer your patients: Canada-wide research study on COVID-19 medications

A national research study evaluating the effectiveness of existing and emerging COVID-19 medications has started participant enrollment in Ontario.

CanTreatCOVID research study aims to identify effective, affordable and evidence-based medications for COVID that would reduce emergency department visits and hospital stays and help people feel better faster. The long-term goal of the study is to find medications that prevent long COVID (refers to a set of symptoms that persist for weeks or months after recovery from acute SARS-CoV-2 infection).

The study is open to adults aged 18-49 years with one or more chronic condition(s) OR adults aged 50+ years who tested positive for COVID-19 within the last five days.

Our first intervention arm is nirmatrelvir/ritonavir (Paxlovid) x 5 days, and other outpatient therapeutics will be added onto the trial based on recommendations from the Canadian COVID-19 Out-Patient Therapeutics Committee.

All participants are able to receive standard of care (outside of the trial), regardless of whether they are assigned to an intervention arm in CanTreatCOVID or not.

Primary care providers can refer participants to the study via

- Phone: 1-888-888-3308 (Monday- Friday; from 8am-6pm EST)
- Email: info@CanTreatCOVID.org
- Website: CanTreatCOVID.org/contact

Supported by $10 million in grants from the Canadian Institutes of Health Research and Health Canada, CanTreatCOVID partners with more than 30 organizations across six provinces: Ontario, Quebec, British Columbia, Alberta, Manitoba, and Newfoundland and Labrador. Participant enrollment in other sites will begin soon.

In addition to studying whether any acute treatment can prevent long COVID, CanTreatCOVID will build this adaptive platform trial to be useful for other respiratory infections and help with future pandemics.

CanTreatCOVID study is based at MAP Centre for Urban Health Solutions, Unity Health Toronto and led by Dr. Andrew Pinto, Public Health and Preventive Medicine Specialist, Family Physician, and Founder & Director of the Upstream Lab.

**Learn more about the study**

## CanTreatCOVID Frequently Asked Questions

### PARTICIPANTS

**Who can participate in the study?**

- Adults, regardless of their COVID vaccination status, who tested positive for COVID within 5 days of symptom onset and are:
- 50+ years or
- 18-49 years with one or more chronic condition(s)

**How to participate?**

- Call 1-888-888-3308 (Monday-Friday, from 8am-6pm EST)
- Email info@CanTreatCOVID.org
- Visit CanTreatCOVID.org/contact

**What will participants do?**

- Either take a study drug or follow usual care recommendations from public health.
- Complete a daily diary from Day 1 to 14 (online or by phone call)
- Answer follow-up calls on Day 21, 28, 90 and Week 36.

**Is there a cost to participate in the study?**

- There are no costs associated with participating in the study. If participants are randomized to the treatment arm, they will receive the study drug for free.

**Is there an honorarium?**

- Participants will receive $30 for each follow-up (Day 21, 28, 90 and Week 36).

### REFERRAL

**Who can refer participants to the study?**

- Anyone can refer adults with a positive COVID test who are aged 50+ years or 18-49 years with one or more chronic condition(s).
- Participants may also contact the study team directly.

**How to refer participants?**

- Call 1-888-888-3308 (Monday- Friday; from 8am-6pm EST)
- Email info@CanTreatCOVID.org
- Visit CanTreatCOVID.org/contact

## TRIAL SCREENING ASSESSMENT

- **Step One: Research Assistant Screening**

The research assistant will go through a series of questions with potential participants to determine if they meet the inclusion and exclusion criteria for the study. These questions include demographic information, current health status, and any previous medical conditions or treatments.

- **Step Two: Medication Review by Study Pharmacist**

If participants are potentially eligible, they will then be connected with a study pharmacist who will review their current medication list to ensure that they are not taking any prohibited drugs. This will help to ensure that any potential interactions or contraindications with the study medication are identified before the participant is enrolled.

- **Step Three: Final Eligibility Review by Study Physician**

As the final step, the study physician will review the participant's medical history and medication history to confirm their eligibility. The physician will also ensure that the participant meets the inclusion and exclusion criteria and that they have provided informed consent to participate in the study.
This process helps to ensure that only eligible and suitable participants are enrolled in the study, and that the results of the study are accurate and reliable. It also helps to protect safety and well-being of the participants.

## AFTER ENROLLMENT

**How can participants get the treatment arm if they are isolating?**

- If participants are randomized to the treatment arm, we will ship the study drug to the participants for free.
- Shipment of the study drug takes approximately 24 hours.

**What are the supports available to participants?**

- Participants will be closely monitored by a healthcare team, which helps to ensure that any side effects or complications are identified and addressed quickly.
- Participation in this study provides patients with personalized care and attention, as well as access to specialized resources and support.

**What happens if participants withdraw from the study after receiving the study drug?**

- Participants may decide to complete the study treatment course.

**What happens if patients cannot take a treatment arm due to drug interactions?**

- Depending on the specific circumstances, based on recommendations from the study pharmacist, the study physician may decide to end treatment for certain participants, but participants may still be asked to continue completing daily diaries and participating in follow-up phone calls to provide ongoing data for the study.

**Will participants be informed if they received treatment or not?**

- Yes, CanTreatCOVID is an open-label study and participants will know if they are randomized to receive the study drug or follow usual care recommendations from public health.

**Are translations available for participants?**

- Yes, the study forms and questionnaires are available in French and English and if needed, additional languages will be added to accommodate study participants.
- If potential participants are unable to communicate in English or French, the study staff may refer the consenting process to someone within the study team that speaks the required language or ask to speak with an alternate contact who is able to communicate in English or French.

## SIGNIFICANCE OF THE STUDY

**Why should patients participate in the study if they can just go to the pharmacy to get a prescription for Paxlovid?**

Patients may choose to participate in a study for several reasons:

1. Close monitoring: In this study, patients will be closely monitored by a healthcare team, which helps to ensure that any side effects or complications are identified and addressed quickly.
2. Personalized care: Participation in this study provides patients with personalized care and attention, as well as access to specialized resources and support.
3. No cost: We cover the cost of treatment and related expenses, so patients do not have to pay for their care.
4. Contribution to medical research: By participating in this study, patients are contributing to the identification of the most effective therapeutics for non-

hospitalized COVID-19 patients, advancing of our understanding of the disease and improving treatment options for future patients.

It's important to consider that participating in this study is voluntary and that patients can always decide not to participate or to withdraw from the study at any time.

**Why refer patients to participate in this study?**

1. This will help you save time. You can refer adults who tested positive for COVID to our study, and we will screen if they are eligible to receive COVID medications, including nirmatrelvir/ritonavir (Paxlovid).

2. This study is the fastest way to answer whether these medications are effective, particularly in a highly vaccinated population.

3. This is **by** primary care providers, for primary care providers! CanTreatCOVID is helping us launch the new Canadian Primary Care Trials Network, finally creating evidence in the real world of primary care.

**What are the other treatment arms other than Paxlovid?**

- CanTreatCOVID will go beyond nirmatrelvir/ritonavir (Paxlovid) x 5 days. There is a strong interest in incorporating the following interventions as a treatment arm in this research project: nirmatrelvir/ritonavir x 10 days, fluvoxamine, budesonide, antioxidant supplement, etc.