CanTreatCOVID

Canadian Adaptive Platform Trial of Treatments for COVID in Community Settings

About the study

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. Supported by the Canadian Institutes of Health Research, Health Canada and Public Health Agency of Canada, the long-term goal of CanTreatCOVID is to find medications that prevent post-COVID condition, also known as long COVID.

Objectives

- Evaluate the effectiveness of existing and emerging treatments for acute COVID-19 in primary care and community settings. Importantly, CanTreatCOVID will go beyond nirmatrelvir/ritonavir (Paxlovid).
- Study whether any acute treatment can prevent long COVID.
- Build this adaptive platform trial to be useful for other respiratory infections and help with future pandemics.

Who can participate?

- Adults who tested positive for COVID with symptoms starting within the last 5 days and
- Aged 18-49 years with one or more chronic condition(s) **OR** aged 50+ years regardless of health status
- Living in Ontario, Quebec, British Columbia, Alberta, Manitoba, or Newfoundland and Labrador

To learn more, visit **CanTreatCOVID.org** or contact

1-888-888-3308 **info@CanTreatCOVID.org**

scan to visit the study website

Version 3; February 7, 2023

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 would prevent post-COVID condition, also known as long COVID.

The study is open to adults who tested positive for COVID-19 with symptoms starting within the last five days and aged 18-49 years with **one or more chronic condition(s)** OR adults aged 50+ years regardless of their health status.

Participation in the study is online and involves receiving a study drug or usual care, completing a daily diary for 14 days, and answering follow-up calls or surveys. The study will provide up to $150 compensation to participants.

Our first intervention arm is nirmatrelvir/ritonavir (Paxlovid) x 5 days and we will add other outpatient therapeutics to the trial based on recommendations from the Canadian COVID-19 Outpatient Therapeutics Committee.

Primary care providers or anyone can refer participants to the study by asking them to

- Call 1-888-888-3308 (Monday - Friday from 8am - 6pm EDT) or
- Email **info@CanTreatCOVID.org** or
- Complete the pre-screening form: **https://redcap.link/CanTreatCOVID**

Supported by the Canadian Institutes of Health Research, Health Canada and Public Health Agency of 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 with symptoms starting within the last 5 days and
- 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 EDT)
- Email **info@CanTreatCOVID.org**
- Visit **CanTreatCOVID.org/contact**
- Complete the pre-screening form: **https://redcap.link/CanTreatCOVID**

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 a compensation for participants?

- 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 8 am - 6pm EDT)
- Email **info@CanTreatCOVID.org**
- Visit **CanTreatCOVID.org/contact**

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.

TRIAL SCREENING ASSESSMENT

We will conduct a risk assessment to verify that individuals meet the study eligibility criteria and are able to receive the study drug, including Paxlovid. This process will consist of three steps:

- **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.

Additional Exclusion Criteria for Paxlovid
Paxlovid is contraindicated for use in individuals who:

- ✓ are pregnant or have a known or suspected pregnancy
- ✓ are breastfeeding
- ✓ have the potential to bear children and are unwilling to use effective contraception
- ✓ have a history of hypersensitivity to nirmatrelvir/ritonavir or any of its excipients
- ✓ have galactose intolerance, lactase deficiency, or glucose-galactose malabsorption
- ✓ have severe liver impairment
- ✓ have moderate or severe renal disease (defined as CKD stage 3, 4 or 5 or current acute kidney injury or most recent eGFR in the past 6 months <60 ml/min)*
- ✓ are currently taking Paxlovid
- ✓ are taking a drug that is contraindicated or not recommended for use with Paxlovid

* Please note that individuals with a GFR of 30-60 ml/min must take a reduced dose of Paxlovid and will not be eligible to participate in the CanTreatCOVID study, as all participants must receive the same dose.

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 are we doing this research?

- Existing studies have been in unvaccinated patients. It is unclear whether and to what extent existing treatments (including Paxlovid) are effective in partially or fully vaccinated patients.
- Existing knowledge about COVID treatments (including Paxlovid) is mostly based on observational studies. We need high-quality evidence to further understand the effectiveness of COVID medications.

- Currently, no treatment has been evaluated specifically for its potential to prevent long-term symptoms of COVID (long COVID).

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 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.

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.