CONTROL COVID

CONTROL OF COVID-19 OUTBREAKS IN LONG TERM CARE

A collaboration between

TIBDN Toronto Invasive Bacterial Diseases Network

AHRC Applied Health Research Centre

CO-ORDINATING INVESTIGATOR

Dr. Allison McGeer
416-586-4800 EXT 3123
Allison.McGeer@sinaihealth.ca

CO-INVESTIGATORS

Dr. Eric Coomes
Dr. Peter Jüni
Dr. Andrew Simor
Dr. Adrienne Chan
Dr. Rhonda Collins
Dr. Bruno DaCosta
Dr. Nick Daneman
Dr. Carol Epstein
Dr. Frederick Hayden
Ms. Alainna Jamal
Dr. David Juurlink
Dr. Christopher Kandel
Dr. Kevin Katz
Dr. Tony Mazzulli
Dr. Mohammad Mozafarihasjin
Dr. Samira Mubareka
Dr. Elizabeth Rea
Dr. Darrell Tan
Dr. Kevin Thorpe

TIBDN OFFICE:
Sinai Health
600 University Avenue
Room 171
Toronto, ON M5G 1X5
1-416-586-4800, ext 2763
Fax: 416-586-8894

AHRC OFFICE:
Unity Health
250 Yonge St.
Toronto, ON
M5G 1B1
1-416-864-6060, ext 3037

Research Study : CONTROL of COVID-19 Outbreaks in Long Term Care
Information for Medical Directors and facility physicians

Dear Dr. _____,

Early on in the global spread of the COVID-19 pandemic, it became apparent that frail older adults are disproportionately bearing the burden of this pandemic. It is clear that developing interventions to more effectively control COVID-19 outbreaks in LTCHs is an urgent need.

Chemoprophylaxis has been a cornerstone in the management of LTCH influenza outbreaks. Although chemoprophylactic agents for COVID-19 do not yet exist, there is *in vitro* testing suggesting that some existing antiviral agents may be effective. Favipiravir, a broad-spectrum anti-viral agent has exhibited in *vitro* activity against SARS-CoV-2 and has demonstrated benefit in early COVID-19 clinical studies. This drug is an ideal candidate for chemoprophylaxis, with a favourable safety profile and oral formulation.

We propose a cluster-randomized placebo-controlled clinical trial of favipiravir chemoprophylaxis for the control of COVID-19 outbreaks in LTCHs. LTCH units with an outbreak of COVID-19 (2 or more residents with symptomatic COVID-19 within 7 days) will be eligible for enrollment. The trial will enrol residents and staff of 16 LTCH units with outbreaks of COVID-19 in Ontario.

LTCH units with outbreaks will be randomized to receive favipiravir or placebo in a 1:1 ratio. Consenting residents and staff of these units will receive the study drug simultaneously and will continue chemoprophylaxis for 25 days. This design mimics the current approach to outbreaks of influenza, which has proven effective for outbreak control.

If you, the administration, and the residents' council of this long term care home agree to the study, we will share information about the study with residents, staff and substitute decision makers. If an outbreak of COVID-19 occurs on a unit in this home, residents and any staff or physicians who will be working on the units will be approached for consent to participate. Staff will be followed for 40 days, and residents for 60 days. Other than study drug, the study will not make any recommendations regarding care; your care for residents will not change, and you may of course discontinue the study medication if you believe it to be best for the resident. The only other study intervention will be nasal swabs for COVID-19 to be obtained from all consenting residents and staff on days 0, 14, and 40. A study doctor will be available on-call to talk to you at any time you are worried about an adverse event from a medication or have other questions about the study.

We are very much hoping that you will agree that this study is of value for your patients who are residents in LTC. More information is available on our website at www.tibdn.ca/control-covid.

Study investigators are available at any time if you have questions or comments. I can be reached at 416-586-3123 or Allison.mcgeer@sinaihealth.ca.

Thank you for your consideration.

Sincerely,

Allison McGeer, MD, FRCPC
on behalf of the CONTROL-COVID Investigators