CATCO

A Multi-centre, Adaptive, Randomized, Double-Blind, -Controlled Clinical Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Patients

This is a multi-centre, adaptive, randomized, double-blind, controlled clinical trial to evaluate the efficacy and safety of investigational therapeutic agents in combination with standard-of care for the treatment of hospitalized patients with novel coronavirus disease (COVID-19).
This Protocol is largely based on a series of deliberations of the WHO R&D Blueprint Clinical Trials Expert Group. The experts included international clinical trialists, coronavirus experts, regulatory and ethics experts and clinicians, including those treating COVID-19 patients .
Based on those deliberations, experts at the National Institute of Allergy and Infectious Diseases (NIAID) at the US National Institutes of Health developed the full version of the protocol. The version was then further adjusted to facilitate its implementation internationally.

Sites participants :
20 centers across Canada.

Objectifs du projet :
The overall objective of the study is to evaluate the clinical efficacy of different investigational therapeutics relative to the control arm in adult and pediatric patients hospitalized with COVID-19.

Méthodes :
This study is an adaptive, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of novel therapeutic agents in hospitalized children and adult patients diagnosed with COVID-19. The study is a multicentre trial that will be conducted in up to 20 sites in Canada. The study will be a series of 2-arm comparisons between different investigational therapeutic agents and a control arm. There will be interim monitoring to introduce new arms and allow early stopping for futility, efficacy, or safety. If one therapy proves to be efficacious, this treatment will then become the control arm for comparison(s) with new experimental treatment(s). Because of the possibility that background standards of supportive care may vary between centres and evolve/improve over time as more is learned about successful management of COVID-19, comparisons of safety and efficacy will be based on data from concurrently randomized participants. An independent data and safety monitoring board (DSMB) will actively monitor interim data to make recommendations about early study closure or changes to study arms.

Résultats attendus :

Outcome will be the proportions of patients achieving a defined ordinal scale outcome at day 28, as agreed upon by WHO Master Protocol core outcomes set. The 8-point ordinal scale will also be determined at day 7, 14, 21, and hospital discharge. Secondary outcomes will include time to viral clearance in nasopharyngeal swabs and stool (taken every two days while hospitalized), hospital mortality, ventilator-free days (of 28 days),24 and hospital length-of-stay (separately among survivors and those who died). Safety data will be collected and reported as a secondary outcome through adverse event reporting.