COVID-19 PEP RCT

Information about the research:

We are conducting a research study in Quebec, Manitoba, and Alberta to determine if taking a medication called hydroxychloroquine can prevent you from getting sick with COVID-19. COVID-19 is a disease caused by a coronavirus (SARS-CoV2) that causes a flu like illness, including cough, fever, shortness of breath, and in some cases pneumonia.

This study will assess if the use of hydroxychloroquine after exposure, but prior to the onset of symptoms will reduce the risk of developing COVID-19 disease and/or reduce the severity of illness should disease occur. In another group of individuals, we will also assess if the early use of hydroxychloroquine, shortly after the onset of symptoms of COVID-19 disease, will shorten the duration of their symptoms, and reduce their symptom severity.

In NON-HUMAN studies in the laboratory, researchers have identified chloroquine and hydroxychloroquine have activity against SARS coronaviruses.

Both chloroquine and hydroxychloroquine are Health-Canada approved medications that have been used to prevent infection from malaria since the 1950s. Recent work has shown that hydroxychloroquine may be more active than chloroquine against the current SARS-CoV2 virus that causes COVID-19 disease. The hydroxychloroquine dose used in this study is similar to what is being given for malaria treatment. It is a very safe medication, especially when used in short periods. The most common side effect is upset stomach and is usually mild. Serious side effects can occur, but generally only when taken for prolonged periods such as > 1 year.

No clinical trials have been completed to determine if this medicine is effective in preventing or treating COVID-19 disease in humans. Current trials in China and France are also testing chloroquine and hydroxychloroquine as treatment for patients sick with COVID-19 disease. As the COVID-19 pandemic spreads to Canada and other areas of the world, there is a need for new preventative measures for those exposed to the coronavirus. There is some evidence that hydroxychloroquine may be helpful to reduce COVID-19, but we don’t really know if its effective or not. This study will help us determine if this drug should be used routinely to prevent and/or treat early symptoms of COVID-19.

This study is being conducted through the University of Manitoba, in conjunction with researchers at the University of Minnesota, University of Alberta, and the Research Institute of the McGill University Health Centre.
Who might be eligible for this research study?

We are seeking research volunteers who have COVID-19, or those with exposure to individuals with COVID-19. You may be eligible to participate if you meet the following conditions:

**Adults without symptoms, and exposed to a COVID-19 case**
1) You may be eligible if you are a household contact (share residence) with a person known to have COVID-19, the exposure to that person occurred within the past 4 days, and you currently have no symptoms
2) You may be eligible if you are a healthcare worker with a moderate to high risk contact with a patient known to have COVID-19, the contact occurred within the past 4 days, and you currently have no symptoms

**Adults with symptoms of COVID-19 (fever and/or cough and/or shortness of breath)**
1) You may be eligible if you have a confirmed diagnosis of COVID-19 (from testing), your symptoms began within the past 4 days, and you are currently self-isolating (not in hospital).
2) You may be eligible if you are a healthcare worker experiencing symptoms for 4 days of less and had contact with a patient confirmed to have COVID-19 within the last 14 days

**Purpose of the research:**

1) To determine if taking hydroxychloroquine can prevent COVID-19 disease after an exposure to the SARS-CoV2 coronavirus. Importantly, we do not know if this medicine will be effective at preventing COVID-19. We will compare the effectiveness of hydroxychloroquine to a medication that has no effects on the SARS-CoV2 coronavirus (placebo). If effective, this may become a worldwide standard of care, helping to prevent disease in other people exposed around the world.
2) To determine if taking hydroxychloroquine given early after symptom onset of COVID-19 (before patients are in hospital) can prevent disease progression and hospitalization. Currently, no known therapies are effective at reducing symptoms and preventing disease progression to more serious stages. We will compare hydroxychloroquine to placebo to determine if the medication is effective and should be given to other people showing early symptoms of COVID-19.

**What you will need to do:**

To determine if you are eligible, you will need to do the following:

- Email covid19FAQ@idtrials.com
- You will be sent an online screening questionnaire, complete this and submit it
- If determined eligible, review the study documents and consent to participation
• Study medication will be delivered to your home within 24 hours

If you are eligible, and you consent to participate in this trial, you will be asked to take the medicine sent to you over a period of 5 days, and to complete online surveys, typically over a span of 14 days. The typical schedule from participation in this study is as follows:

• Agree to be randomly assigned to receive hydroxychloroquine or placebo. If you agree to this study, there is 50-50 chance of receiving placebo, or hydroxychloroquine. You will not know if the study medicine you receive is hydroxychloroquine or placebo.

• Day 1
  o Complete online survey – to confirm receipt of medications, delivered to your home address (within 24 hours)
  o Take 4 tablets of the study medicine by mouth once
  o Take another 3 tablets of the study medicine by mouth 6-8 hours later

• Day 2 to 5
  o Take 3 tablets of the study medicine by mouth once each day in the mornings
  o If you have symptoms, a survey will be sent for completion on day 3
  o On day 5, a survey will be sent for completion and the study medicine will be finished

• Day 10
  o Complete an online survey if you had symptoms at the beginning of the study or if you developed symptoms during the study

• Day 14
  o Complete an online survey
  o If you do not have symptoms, this is your last task
  o If you do have symptoms, we will contact you for further instructions

*Please note, if you take other medicines prescribed by your doctor, you must separate these medications from the study medicine by 4 hours.
*If you develop upset stomach with the study medication, you can separate the tablets throughout the day (example: 2 at breakfast, 1 at lunch)
*No in person visits, and no samples from your body will be collected during this study.

How do I determine if I am eligible?

To determine your eligibility to participate in this study, email us at:
covid19FAQ@idtrials.com

How do I contact the research team if I have questions?

For general questions about this research study, contact:
covid19FAQ@idtrials.com