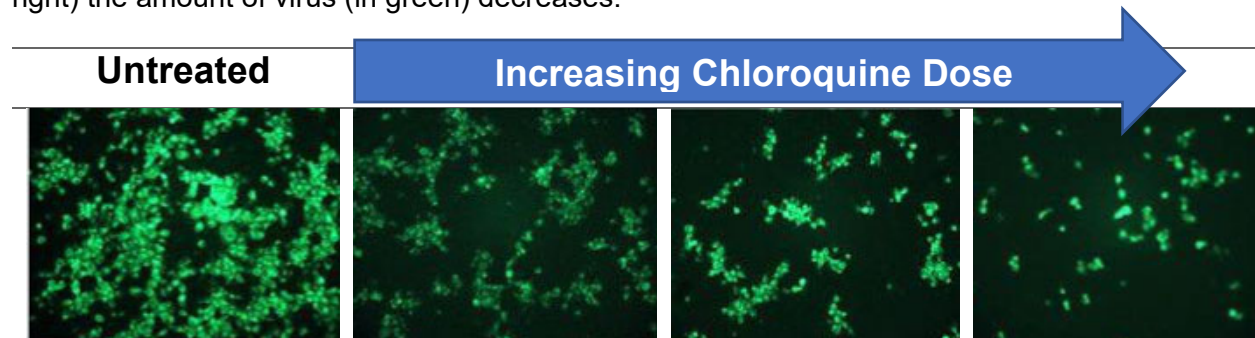


Information on COVID-19 Post-Exposure Prophylaxis or Preemptive Therapy Trials

The University of Minnesota is conducting a research study to determine if taking a medication called hydroxychloroquine can help in preventing or treating COVID-19 disease (commonly referred to as coronavirus). The study will be conducted among:

- 1) Household contacts with known exposure to someone with COVID-19 within the last 4 days and who are currently asymptomatic; OR
- 2) Healthcare workers with known exposure to someone with COVID-19 within the last 4 days and who are currently asymptomatic; OR
- 3) Individual who is symptomatic with confirmed COVID-19 test within the first 4 days of symptoms; OR
- 4) Household contact or Healthcare worker with compatible symptoms with exposure to known PCR+ COVID-19 case within 14 days AND compatible symptoms of fever, cough, or shortness of breath and no available testing or pending testing for the individual.

In laboratory studies, researchers have identified two medicines, chloroquine and hydroxychloroquine, as having activity against SARS-coronaviruses. The images below show SARS-CoV-1 virus as fluorescent green. As increased doses of chloroquine are added (left to right) the amount of virus (in green) decreases.



Images from Vincent et al. Virology Journal 2005; [doi:10.1186/1743-422X-2-69](https://doi.org/10.1186/1743-422X-2-69)

Chloroquine and hydroxychloroquine are FDA-approved medicines that have been used to prevent and treat malaria since the 1950s. Recent work shows that hydroxychloroquine (also known as Plaquenil) may be more active than chloroquine against the SARS-CoV-2 virus.

No clinical trials have been completed to determine if this medicine is effective in preventing or treating early COVID-19 disease in humans. Current trials in China and France are testing chloroquine or hydroxychloroquine as treatment for those sick with COVID-19 disease in the hospital. With the growing coronavirus outbreak in the United States and worldwide, there is a need for new preventive measures for people exposed to the coronavirus.

We are seeking research volunteers who have been:

1. Exposed and without Symptoms

Closely exposed to a person with confirmed PCR+ COVID-19 disease within ≤ 4 days;

AND

Are a household contact or a healthcare worker;

OR

2. With Symptoms

- Currently diagnosed with **known** COVID-19 disease within ≤ 4 days of symptom onset, OR
- Household contact or Healthcare worker with **known** COVID-19 contact and compatible symptoms with pending/unavailable testing within ≤ 4 days of illness onset.
- Not hospitalized

The purpose of this research study is to determine if taking the medication hydroxychloroquine can prevent a person who has been exposed to the coronavirus from becoming ill and possibly reducing the severity of illness. Importantly, we do not know if this medicine will be effective at preventing disease. To determine if hydroxychloroquine is an effective medication in preventing disease in those exposed to the coronavirus, we will compare the effectiveness of hydroxychloroquine to a medication that has no effects on the coronavirus. If effective, this may become a worldwide standard of care helping prevent disease in other healthcare workers and people exposed around the world.

If you consent to participate, we will ask you to:

- Agree to be randomly assigned to receive hydroxychloroquine or a vitamin. If you agree to this study, there would be a 50-50 chance of receiving a vitamin instead of hydroxychloroquine.
- Take the study medicine for **five** days.
 - ON DAY 1
 - take 4 tablets by mouth at once, then
 - 6-8 hours later take 3 tablets, then
 - ON DAYS 2 – DAYS 5
 - take 3 tablets once per day
- Answer 3-5 short follow up email surveys:
 - Day 1 (to confirm you have received the medicines)
 - Day 3 (if you had symptoms on Day 1)
 - Day 5
 - Day 10
 - Day 14
 - If you become ill or are hospitalized, we would ask to contact you to determine how long your illness lasts.

The hydroxychloroquine dose in this study is similar to what is given for malaria treatment. It is a very safe medicine when used for short periods. The most common side effect is upset stomach and is usually mild. Other side effects reverse when stopping. Serious side effects can occur, but generally only when taken for extended periods, generally >1 year of continuous use.

To determine your eligibility to participate, go to trialcovid.com or email covid19@umn.edu
(You will get an immediate response with instructions, if not please check your spam folder)

If you are eligible to participate, we will ship the study medicine to you overnight. For further general questions about the research study, please e-mail: covid19FAQ@umn.edu
Persons in Canada, please go to: www.covid-19research.ca