

Hydroxychloroquine Trial Announced April 1st, 2020

ClinicalTrials.gov Identifier: NCT04329611

Recruitment Status : Recruiting

First Posted : April 1, 2020

Last Update Posted : May 18, 2020

See [Contacts and Locations](#)

Trial Cancelled – Lancet Article Published May 22nd. Retracted **June 4th**.

Trial updated on cancellation two weeks **AFTER** lancet article is retracted on June 17th!

ClinicalTrials.gov Identifier: NCT04329611

Recruitment Status : Suspended (Enrolment was suspended on 22may2020, after Mehra et al (Lancet 2020) suggested excess toxicity of HCQ.)


First Posted : April 1, 2020


Last Update Posted : **June 17, 2020**


Called out publicly on July 27th, 2020 about Alberta Literally having No Hope!

ALBERTA HOPE COVID-19 for the Prevention of Severe COVID19 Disease

ClinicalTrials.gov Identifier: NCT04329611

Recruitment Status  : Suspended (Enrolment was suspended on 22may2020, after Mehra et al (Lancet 2020) suggested excess toxicity of HCQ.)

First Posted  : April 1, 2020

Last Update Posted  : June 17, 2020

STILL NO HOPE
FOR ALBERTA
July 27th, 2020

Updated on July 31st, 2020 to suggest a lack of cases!

ClinicalTrials.gov Identifier: NCT04329611

Recruitment Status : Terminated (Enrolment was suspended on 22may2020, after Mehra et al (Lancet 2020) then stopped due to lack of Covid19 cases.)

First Posted : April 1, 2020

Last Update Posted : July 31, 2020

Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis

Mandeep R Mehra, Sapan S Desai, Firsiroti Ruschitzka, Amit N Patel

Summary

Background Hydroxychloroquine or chloroquine, often in combination with a second-generation macrolide, are widely used for treatment of COVID-19 despite no conclusive evidence of their benefit. Although these drugs have been used for approved indications such as autoimmune disease or malaria, the safety and benefit of these treatment regimens are poorly evaluated in COVID-19.

Methods We did a multinational registry analysis of the use of hydroxychloroquine with or without a macrolide for treatment of COVID-19. The registry comprised data from 671 hospitals in 35 countries. We included patients hospitalised between Dec 20, 2019, and April 14, 2020, with a positive laboratory test for SARS-CoV-2. Patients who received one of the treatments of interest within 48 h of diagnosis were included in one of four treatment groups (chloroquine alone, chloroquine with a macrolide, hydroxychloroquine alone, or hydroxychloroquine with a macrolide), and patients who received none of these treatments formed a control group. Patients for whom one of the treatments of interest was initiated more than 48 h after diagnosis or while they were on mechanical ventilation, as well as patients who received remdesivir, were excluded. The main outcome of interest was in-hospital mortality and the occurrence of de-novo ventricular arrhythmias (defined as sustained ventricular tachycardia or ventricular fibrillation).

Findings 96032 patients (mean age 53.8 years, 46.1% women) with COVID-19 were hospitalised during the study period and met the inclusion criteria. Of these patients, 1868 were in the treatment groups (1868 received chloroquine, 3783 received chloroquine with a macrolide, 3016 received hydroxychloroquine, and 6221 received hydroxychloroquine with a macrolide) and 6221 were in the control group. 10,098 (11.1%) patients died in hospital. After controlling for multiple confounders (age, sex, race or ethnicity, body-mass index, underlying cardiovascular disease and its risk factors, diabetes, underlying lung disease, smoking, immunosuppressed condition, and baseline disease severity), we compared mortality in the control group (9.3%), hydroxychloroquine (18.0%; hazard ratio 1.335, 95% CI 1.239–1.447), hydroxychloroquine with a macrolide (23.8%; 1.447, 1.368–1.531), chloroquine (16.4%; 1.365, 1.278–1.453), and chloroquine with a macrolide (22.2%; 1.368, 1.273–1.467) were each independently associated with an increased risk of in-hospital mortality. Compared with the control group (0.3%), hydroxychloroquine (6.2%; 2.176, 95% CI 1.909–7.090), hydroxychloroquine with a macrolide (8.1%; 3.106, 4.106–5.983), chloroquine (4.3%; 1.511, 1.365–4.596), and chloroquine with a macrolide (6.5%; 4.011, 3.344–4.812) were independently associated with an increased risk of de-novo ventricular arrhythmia during hospitalisation.

Interpretation We were unable to confirm a benefit of hydroxychloroquine or chloroquine, when used alone or with a macrolide, on in-hospital outcomes for COVID-19. Each of these drug regimens was associated with decreased in-hospital mortality, but also with an increased frequency of ventricular arrhythmias when used for treatment of COVID-19.

Funding William Gray Distinguished Chair in Advanced Cardiovascular Medicine at Brigham and Women's Hospital.

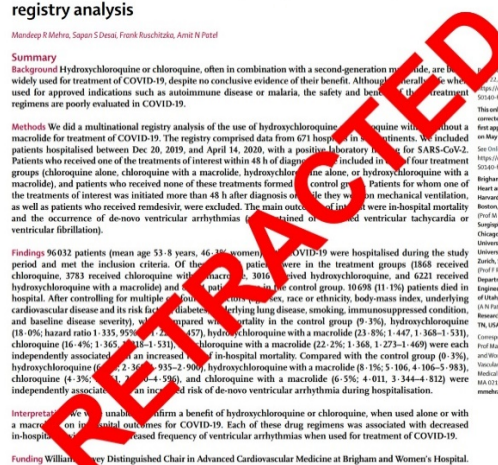
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Introduction

The absence of an effective treatment against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has led clinicians to redirect drugs that are known to be effective for other medical conditions to the treatment of COVID-19. Key among these repurposed therapeutic agents are the antimalarial drug chloroquine

drugs have been shown in laboratory conditions to have antiviral properties as well as immunomodulatory effects.¹ However, the use of this class of drugs for COVID-19 is based on a small number of anecdotal experiences that have shown variable responses in uncontrolled observational analyses, and small, open-label, randomised trials that have largely been

Articles



The Reality.

At the time of the Trial Alberta had 13 cases per 100,000 ↓

At the time the trial was put on hold for the Lancet article Alberta had 18 cases per 100,000 ↓

At the time the trial was put on hold for a lack of cases Alberta had 31 cases per 100,000. ↓

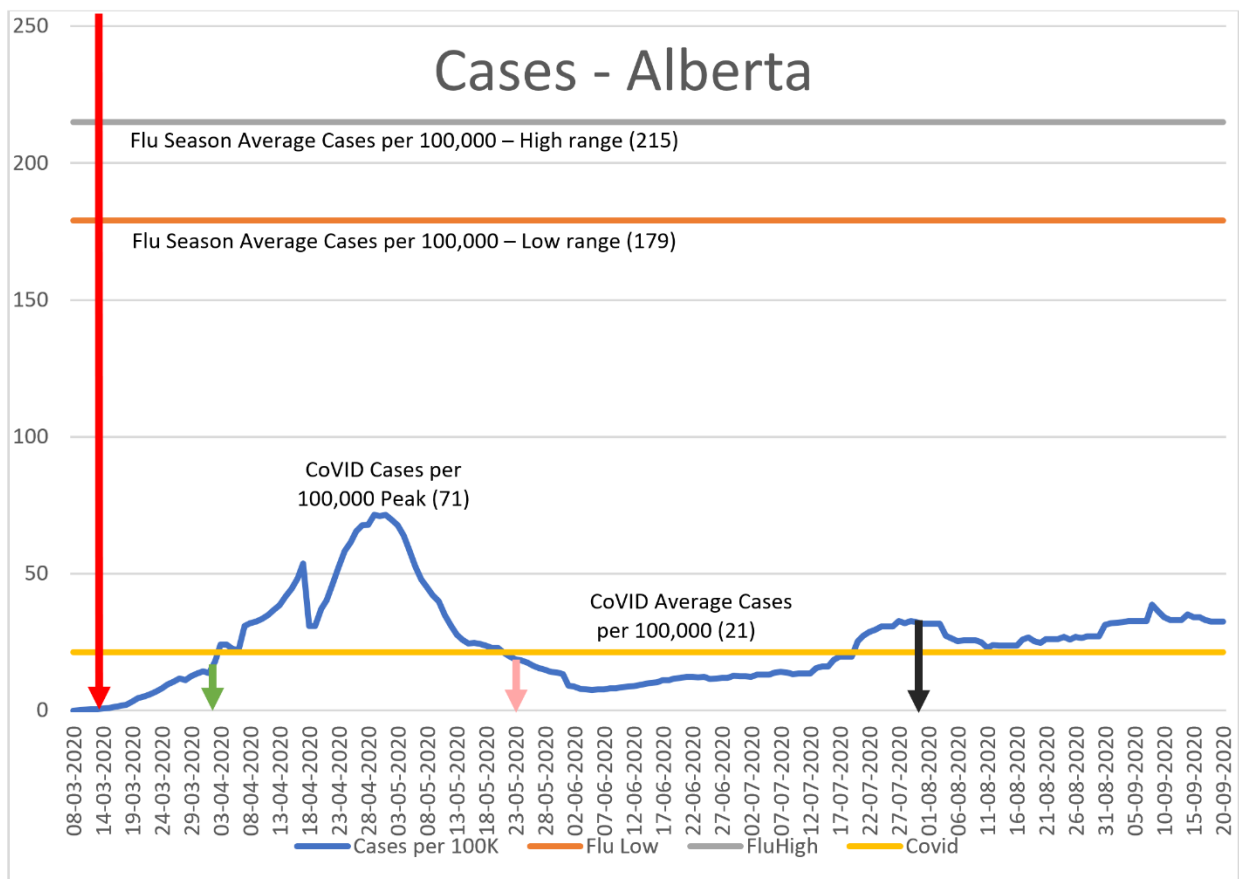
Alberta cases per 100,000 have not dropped below **23** since.

All of this triggered by a case rate of **0.4** per 100,000 on March 12th, 2020 when any gathering of more than 250 people was banned. This shut down most businesses, especially retail, immediately.

This was five days before Deena Hinshaw called a state of emergency with **1.69** Cases per 100,000

Flu season for the last few years have been between 179 and 219 cases per 100,000. Note that the flu rate is calculated on gold standard lab confirmed flu testing from hospitalisations. This underestimates the actual flu infections.

CoVID cases are based on unreliable tests and assumed cases so are most likely overinflated.



Welcome to your new health care.

The trial itself seemed designed to fail even if it started and could be described as medical negligence by design.

To qualify you had to be sick, test positive and have co-morbidities, making a poor outcome highly likely within a week or so. However, if you qualified, you were sent the medication through the mail for a 5-day dose without any zinc or antibiotic or medical supervision. This was already known to be a flawed approach from many previous studies. The follow up was by phone up to 30 days later. The reality is, if the drug and disease were as dangerous as they suggested, they would be counting bodies at the end of the trial.

“Those who are eligible will be randomized to receive HCQ or placebo for a total duration of 5 days. Study drug will be delivered to their residence by courier. Telephone follow-up will occur at day 7 (range 7-10 days) and at day 30 (range 25-35 days).”

Brief Summary:

Albertans with COVID-19 are at risk of deteriorating and developing severe illness. **Those over age 40 or with co-morbid illness, and likely those who are immune suppressed**, are at highest risk. **This study will include a focus on people with immune-suppressed states.** Individuals confirmed to have **SARS-CoV-2 infection will be identified using administrative data (positive lab result, age 18 or over, not hospitalized, and not living in SL4 level of care).** **They will then be contacted by AHS staff, independent of the researchers, to obtain their consent for the researchers to contact them about this trial.** The AHS staff member who contacts the individual will enroll consenting individuals into a study database. If they provided an email address an email will automatically be sent to the individual with study information. **Those who decline to be contacted will also be informed of the study website so they can choose to review the study information and self-enrol, although they will need to do so quickly to meet study timelines.** Enrolled participants will be contacted by a study coordinator. **Those without access to the internet will be informed about the study details when they are contacted by a study coordinator.** When the study coordinator contacts potential participants the study will be reviewed, and the potential participant will have an opportunity to ask questions. **Consent for participation will be obtained by telephone. ...**

Inclusion Criteria:

1. **Confirmed SARS-CoV-2 infection**, defined as RT-PCR provincial laboratory confirmation.
2. Self-reported symptoms of SARS-CoV-2 infection including any of the following: **fever $\geq 37.5^{\circ}\text{C}$, cough, dyspnea, chest tightness, malaise, sore throat, myalgias, or coryza**
3. Time from a positive test result to day 1 of treatment within 4 days
4. Time from patient reported first symptoms to day 1 of treatment within 12 days
5. Adults, age 18 and over, **with any risk factor for severe disease**
6. Resident of Alberta or if not a resident of Alberta able to provide complete follow-up data
7. Agrees to use adequate contraception for the duration of the study
8. **Informed consent**

Drug provided

Hydroxychloroquine 400 mg po bid loading dose for 1 day followed by 200 mg po twice daily for 4 days.