42 comments

Efficacy of hydroxychloroquine in patients with COVID-19: results of a randomized clinical trial

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This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.

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Abstract

Aims: Studies have indicated that chloroquine (CQ) shows antagonism against COVID-19 in vitro. However, evidence regarding its effects in patients is limited. This study aims to evaluate the efficacy of hydroxychloroquine (HCQ) in the treatment of patients with COVID-19. Main methods: From February 4 to February 28, 2020, 62 patients suffering from COVID-19 were diagnosed and admitted to Renmin Hospital of Wuhan University. All participants were randomized in a parallel-group trial, 31 patients were assigned to receive an additional 5-day HCQ (400 mg/d) treatment, Time to clinical recovery (TTCR), clinical characteristics, and radiological results were assessed at baseline and 5 days after treatment to evaluate the effect of HCQ. Key findings: For the 62 COVID-19 patients, 46.8% (29 of 62) were male and 53.2% (33 of 62) were female, the mean age was 44.7 (15.3) years. No difference in the age and sex distribution between the control group and the HCQ group. But for TTCR, the body temperature recovery time and the cough remission time were significantly shortened in the HCQ treatment group. Besides, a larger proportion of patients with improved pneumonia in the HCQ treatment group (80.6%, 25 of 31) compared with the control group (54.8%, 17 of 31). Notably, all 4 patients progressed to severe illness that occurred in the control group. However, there were 2 patients with mild adverse reactions in the HCQ treatment group. Significance: Among patients with COVID-19, the use of HCQ could significantly shorten TTCR and promote the absorption of pneumonia.

Competing Interest Statement

The authors have declared no competing interest.

Clinical Trial

ChiCTR2000029559

Funding Statement

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Author Declarations

All relevant ethical guidelines have been followed; any necessary IRB and/or ethics

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committee approvals have been obtained and details of the IRB/oversight body are included in the manuscript.

Yes

All necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived.

Yes

I understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).

Yes

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

Yes

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Marlowe Fox • 2 days ago

The tests on the efficacy of HCQ are confounded by multiple variables, including comorbidities, symptom onset, prescription drugs (RAAS inhibitors appear to play a key role in viral intensity), and testosterone/estrogen level, to name only a few.

Geneticists, epidemiologists, and other scientists have long used casual diagrams to clearly show variables that may potentially confound their results (1). The Wuhan study at the very least would need to account for the following:

HCQ <— comorbidities —> recovery
HCQ <— symptom onset —> recovery
HCQ <— drug prescriptions —> recovery

Adjusting for the confounding variable would essentially smooth out the flow of information between the treatment (HCQ) and the outcome (recovery), allowing for the inference of causal effects.

Assuming observable data is not available to adjust for confounding variables, a casual mechanism (mediator) could smooth out the flow of information from the treatment to the outcome (so long as the mediator is not influenced by confounder).

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outcome (so long as the mediator is not influenced by confounders).

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Stef Verlinden • 2 days ago

When will this article be published in a peer-reviewed journal? I think this, so far, is the only RCT study that supports the hypothesis that HCQ can prevent exacerbation of disease in COVID-19 patients with CT confirmed mild pneumonia. If correct, its importance can not be underestimated. In that case, early treatment of high-risk patients with HCQ could lead us the way to a faster exit out of the corona crisis...

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Dr Eric Grossi Neurocirurgia • 3 days ago

Here I post the screenshot of Ch CTR data to this study, registry with number : ChiCTR2000029559, everyone can see !

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Dr Eric Grossi Neurocirurgia • 3 days ago

I would like to highlight a serious methodological error in this study. What we want for a drug treatment of COVID-19, only two objectives, to avoid and / or treat SARS and reduce contagion, therefore pragmatism in the selection of patients must be as close as possible to the clinical reality, which did NOT occur, since only patients between the ages of 29.4 to 60 years were analyzed. This alone invalidates any useful result, since the vast majority of human losses are over the age of 64.

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Ty Martin • 4 days ago

Why CQ and not HQ which has been shown to be safer?

2 Reply • Share ›

Ian Sinclair • 4 days ago

This study seems to me potentially of enormous significance. I think it would gain greater acceptance if a) the authors explain why they chose to publish before they had reached the numbers specified in the protocol (100 for TAU and 100 for 4 mg group b) they say why they did not report the results for the 2 mg per day group c) they report the actual data on coughs temperature, numbers improved on radiology examination rather than just the significance levels d) they remedy a minor error in the summary (quotes 32 cases as against 31 e) they confirm that the measures were also made by staff who were blind to allocation f) they got themselves an editor who is a native English speaker. I absolutely do not think that the authors have anything to hide but they need to cope with a Western Audience that has been trained to be ultra critical, looking among other things for investigators who stop a trial the moment that it looks to be going their way. My guess is that this was not the case in this instance and that the study was running out of subjects or the authorities were asking for results or some other event that was out of the control of those running the trial. Given the potential world importance of this trial everyone should be trying to offer constructive suggestions for its greater acceptability rather than

exercising their brains on ways in which mistakes might have been made.

4 ^ | v • Reply • Share ›

Dr Eric Grossi Neurocirurgia ↱ Ian Sinclair • 3 days ago

I'm sorry ... if you make a little research in the Chinese Clinical trial Registry, you are able to see some hole

see more

1 ^ | v • Reply • Share ›