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Effect of hydroxychloroquine on prevention of COVID-19 virus infection among healthcare professionals: a structured summary of a study protocol for a randomised controlled trial

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Abstract

Objectives: Comparison of the effect of hydroxychloroquine with placebo to prevent infection from the COVID -19 virus among healthcare professionals

Trial design: Single centre, 2-arm, double-blind randomised (ratio 1:1) placebo-controlled trial

Participants: Treatment staff who are in contact with patients and have at least 3 shifts a week in Arash hospital affiliated with Tehran University of Medical Sciences, in Iran and who consent to participate in the study. Exclusion criteria include: History of COVID -19 virus infection, clinical symptoms such as fever, nausea, dyspnea and myalgia in the past two months, history of underlying diseases hypersensitivity to hydroxychloroquine and G6PD enzyme deficiency.

Intervention and comparator: Intervention group: Hydroxychloroquine 200 mg tablet of Amin Pharmaceutical. Control group: placebo which is completely similar in form and taste to 200 mg hydroxychloroquine tablet and is manufactured by the same factory (Amin Pharmacy). The dosage is two tablets daily, once a week for one to three months (based on the duration of the Coronavirus epidemic in Tehran).

Main outcomes: Confirmed COVID-19 virus infection using Polymerase chain reaction (PCR) test is the primary outcome. The time period for measuring the primary outcome is any infection within the trial period up to one month after taking the last dose.

Randomisation: The randomized block allocation method was developed using Stata version 15 software by an independent researcher, using a block size of six. Allocation to the two treatment groups will be conducted by this researcher using paper labels (random 10-digit codes) in a 1:1 ratio t The labels will be attached to the drug packages in order of randomization. Drug packages will be arranged in a box according to the randomization list.

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Blinding (masking): Participants and caregivers are blinded to group assignment and the data will be analyzed by an independent statistical expert who is unaware of the treatment allocation.

Numbers to be randomised (sample size): A total of 282 participants will be randomised with 141 participants the Hydroxychloroquineeach intervention group and 141 participants to the placebo control group

Trial Status: The protocol version number is 99-1-101-47091 and the approval ID is IR.TUMS.VCR.REC.1399.001 and recruitment began April 7, 2020, and is anticipated to be complete by August 7, 2020.

Trial registration: The name of the trial register is Iranian registry of clinical trial (IRCT), registration number is IRCT20120826010664N6, date of trial registration is April 7, 2020,

Full protocol: The full protocol is attached as an additional file, accessible from the Trials website (Additional file 1). In the interest in expediting dissemination of this material, the familiar formatting has been eliminated; this Letter serves as a summary of the key elements of the full protocol.

Keywords: COVID-19, Randomised controlled trial, protocol, hydroxychloroquine, healthcare professionals, prevention

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-020-04439-3.

Additional file 1. Full study protocol.

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Authors' contributions
Study design and protocol development: RP, ARD, AM, RMJ, TS, MS. Data analysis: M S. Subject recruitment and follow up: RP, TS, ASH, MR, AM. Manuscript preparation: RP, MS, RMJ. Manuscript review and submission: RP, MS, ARD, AM. The author(s) read and approved the final manuscript.

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Availability of data and materials
Not applicable.

Ethics approval and consent to participate
Ethics committee of Tehran University of Medical Sciences has approved the study, its ethical code is IR.TUMS.VCR.REC.1399.001 and approval was granted on March 22 , 2020 . I certify that this trial has received ethical approval from the appropriate ethical committee as described above. Written consent is obtained from participants to participate in the study.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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