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Preliminary Study on Open Labelled Randomized Controlled Trial of the Safety and Efficacy of Hydroxychloroquine and Chloroquine Phosphate for the Treatment of Persons Infected with 2019 Coronavirus Disease in Nigeria.

Étude préliminaire sur un essai contrôlé randomisé en aveugle ouvert de la sécurité et de l'efficacité de l'hydroxychloroquine et du phosphate de chloroquine pour le traitement des personnes infectées par la maladie du coronavirus 2019 au Nigéria.

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ABSTRACT

BACKGROUND: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a causative agent of COVID-19 is a leading cause of ill-health and deaths worldwide. Currently, COVID-19 has no known widely approved therapeutics. Thus, the need for effective treatment.

OBJECTIVES: We investigated the safety and efficacy of two (2) therapeutic agents; chloroquine phosphate (CQ), 2- hydroxychloroquine (HCQ) and a control (standard supportive therapy) among hospitalized adults with COVID-19.

METHODS: The clinical trial was done in accordance to the World Health Organization master protocol for investigational therapeutics for COVID-19. A total of 40 participants with laboratory-confirmed positive COVID-19 were enrolled. Blood samples and oropharyngeal (OP) swabs were obtained on days 1, 3, 15 and 29 for safety and efficacy assessments.

RESULTS: The baseline demographics showed that the median ages in years (range) were 45 (31–57) in CQ, 45 (36.5–60.5) in HCQ, 43 (39.5–67.0) and 44.5 (25.3–51.3) in the control (P<0.042). At randomization, seven (7) participants were asymptomatic, thirty-three (33) had mild symptoms, eight (8) had moderate symptoms while three (3) had severe symptoms. The average day of conversion to negative COVID-19 was 15.5 days for CQ, 16 days for HCQ and 18 days for the control (P=0.036).

CONCLUSION: The safety assessment revealed no adverse effect of the drugs in COVID-19 patients after treatment. These findings proved that chloroquine and hydroxychloroquine are effective for the treatment of COVID-19 among hospitalized adults. It also confirmed that they are safe. **WAJM 2023; 40(10); 1049-1059.**

Key words: COVID-19, SARS-CoV-2, Clinical trial, safety, efficacy, therapeutics

RÉSUMÉ

CONTEXTE: Le coronavirus du syndrome respiratoire aigu sévère 2 (SARS-CoV-2), agent causal de la COVID-19, est l'une des principales causes de maladie et de décès dans le monde. À l'heure actuelle, il n'existe aucun traitement largement approuvé pour la COVID-19. Ainsi, il y a un besoin de traitement efficace.

OBJECTIFS: Nous avons étudié l'innocuité et l'efficacité de deux (2) agents thérapeutiques, le phosphate de chloroquine (CQ) et l'hydroxychloroquine (HCQ), ainsi qu'un groupe témoin (traitement de soutien standard) chez des adultes hospitalisés atteints de la COVID-19.

MÉTHODES: L'essai clinique a été mené conformément au protocole maître de l'Organisation mondiale de la santé pour les thérapeutiques à l'étude de la COVID-19. Au total, 40 participants atteints de la COVID-19, confirmée en laboratoire, ont été inscrits. Des échantillons de sang et des prélèvements oropharyngés (PO) ont été effectués aux jours 1, 3, 15 et 29 pour évaluer l'innocuité et l'efficacité.

RÉSULTATS: Les données démographiques initiales ont révélé que l'âge médian en années (plage) était de 45 (31–57) pour le groupe CQ, de 45 (36,5–60,5) pour le groupe HCQ, de 43 (39,5–67,0) et de 44,5 (25,3–51,3) pour le groupe témoin (P<0,042). À la randomisation, sept (7) participants étaient asymptomatiques, trente-trois (33) présentaient des symptômes bénins, huit (8) avaient des symptômes modérés, tandis que trois (3) avaient des symptômes graves. Le jour moyen de conversion en test COVID-19 négatif était de 15,5 jours pour le groupe CQ, de 16 jours pour le groupe HCQ et de 18 jours pour le groupe témoin (P=0,036).

CONCLUSION: L'évaluation de la sécurité n'a révélé aucun effet indésirable des médicaments chez les patients atteints de la COVID-19 après le traitement. Ces conclusions ont prouvé que la chloroquine et l'hydroxychloroquine sont efficaces pour le traitement de la COVID-19 chez les adultes hospitalisés. Cela a également confirmé qu'ils sont sûrs. **WAJM 2023; 40(10); 1049-1059.**

Mots-clés: COVID-19, SARS-CoV-2, essai clinique, innocuité, efficacité, thérapeutiques

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ABBREVIATIONS

ACE2 – angiotensin converting enzyme, COVID-19 – Coronavirus disease 2019, CoVs - coronaviruses, CQ - Chloroquine phosphate, DSMB - data and safety monitoring board, ECG – Electro cardiogram, FCT – Federal Capital Territory, HCQ - 2- hydroxychloroquine, HIV – Human immunodeficiency virus, LP/RI - lopinavir boosted with ritonavir, MERS- CoV - Middle Eastern respiratory syndrome coronavirus, NCDC – Nigerian Center for Disease Control, NIMR-IRB – Nigerian Institute of Medical Research Internal review board, OP- oropharyngeal, PCR – Polymerase chain reaction, PICALM - Phosphatidylinositol binding clathrin assembly protein, RDT – Rapid diagnostic test, SARS-CoV-2 - Severe acute respiratory syndrome coronavirus 2, SARS-CoV - Severe acute respiratory syndrome coronavirus, WHO – World Health Organization