



Azithromycin and hydroxychloroquine in hospitalised patients with confirmed COVID-19: a randomised double-blinded placebo-controlled trial

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There are no beneficial or harmful effects from the combined intervention of hydroxychloroquine and azithromycin for hospitalised patients with confirmed coronavirus disease 2019 (COVID-19)
<https://bit.ly/3c0s6XG>

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Abstract

Background Combining the antibiotic azithromycin and hydroxychloroquine induces airway immunomodulatory effects, with the latter also having *in vitro* antiviral properties. This may improve outcomes in patients hospitalised for coronavirus disease 2019 (COVID-19).

Methods Placebo-controlled double-blind randomised multicentre trial. Patients aged ≥ 18 years, admitted to hospital for ≤ 48 h (not intensive care) with a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription PCR test were recruited. The intervention was 500 mg daily azithromycin for 3 days followed by 250 mg daily azithromycin for 12 days combined with 200 mg twice-daily hydroxychloroquine for all 15 days. The control group received placebo/placebo. The primary outcome was days alive and discharged from hospital within 14 days (DAOH14).

Results After randomisation of 117 patients, at the first planned interim analysis, the data and safety monitoring board recommended stopping enrolment due to futility, based on pre-specified criteria. Consequently, the trial was terminated on 1 February 2021. 61 patients received the combined intervention and 56 patients received placebo. In the intervention group, patients had a median (interquartile range) 9.0 (3–11) DAOH14 *versus* 9.0 (7–10) DAOH14 in the placebo group ($p=0.90$). The primary safety outcome,

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death from all causes on day 30, occurred for one patient in the intervention group *versus* two patients receiving placebo ($p=0.52$), and readmittance or death within 30 days occurred for nine patients in the intervention group *versus* six patients receiving placebo ($p=0.57$).

Conclusions The combination of azithromycin and hydroxychloroquine did not improve survival or length of hospitalisation in patients with COVID-19.