Hydroxychloroquine does not reduce mortality, RECOVERY trial finds

Recovery trial

- The RECOVERY trial, a large randomised controlled trial in the U.K. to test five drugs, including hydroxychloroquine, has found no clinical benefit from use of hydroxychloroquine in hospitalised patients with COVID-19.
- The trial investigators found that there was no significant benefit in mortality reduction in the intervention group, which was the primary objective.
- The RECOVERY trial began in March.
- It is a dynamic trial assessing five candidate drugs and convalescent plasma therapy for treating COVID-19 in patients in U.K. hospitals. The trial has enrolled over 11,000 patients.
- On June 4, following the retraction of The Lancet paper on use of hydroxychloroquine, the U.K. Medicines and Healthcare Products Regulatory Agency wanted the independent Data Monitoring Committee of the RECOVERY trial to carry out an additional review.
- It also asked the investigators to look at the unblinded data in the hydroxychloroquine arm.

No beneficial effects

- It then came to light that the drug did not have the desired beneficial effects
- According to the release, a total of 1,542 patients were randomised to receive hydroxychloroquine for 10 days while 3,132 patients in the control arm received only standard care.
- The researchers found that there was “no significant difference in the primary endpoint of 28-day mortality”.
- While mortality was 25.7% in the intervention group (who were administered HCQ), the control group had 23.5% mortality, which is not statistically significant.

Outcomes measured

- The primary outcome tested was reduction in all-cause mortality within 28 days of randomisation.
- The secondary outcomes measured were to assess any reduction in duration of hospital stay and need for and duration of ventilator or ECMO within 28 days and up to six months after randomisation.

Huge speculation

- Deputy Chief Investigator Martin Landray from the University of Oxford says: “There has been huge speculation and uncertainty about the role of hydroxychloroquine as a treatment for COVID-19, but an absence of reliable information from large randomised trials.
- The preliminary results from the RECOVERY trial are quite clear — hydroxychloroquine does not reduce the risk of death among hospitalised patients with this new disease.”

Post-exposure prophylaxis

- Another trial found that hydroxychloroquine drug was not effective even as a post-exposure prophylaxis in asymptomatic participants who have had high-risk exposure
with a confirmed COVID-19 case.

- Nearly 88% (719 of 821 participants) had such high-risk exposure.
- The results of the trial published in The New England Journal of Medicine found that the incidence of COVID-19 illness was not statistically significant in the group that received the drug compared with the control group.
- While 49 of 414 (11.8%) participants who received the drug developed illness, 58 of 407 (14.3%) participants who got the placebo fell ill.
- **Side-effects** were more in the intervention group but no serious adverse events were reported.