UNDER EMBARGO UNTIL 13:00 BST, 8 JUNE 2021





Statement from the RECOVERY trial chief investigators, 8 June 2021

RECOVERY trial finds aspirin does not improve survival for patients hospitalised with COVID-19

The RECOVERY trial was established as a randomised clinical trial to test a range of potential treatments for patients hospitalised with COVID-19. Patients with COVID-19 are at increased risk of blood clots forming in their blood vessels, particularly in the lungs. Between November 2020 and March 2021, the RECOVERY trial included nearly 15,000 patients hospitalised with COVID-19 in an assessment of the effects of aspirin, which is widely used to reduce blood clotting in other diseases.

A total of 7351 patients were randomised to aspirin 150 mg once daily and compared with 7541 patients randomised to usual care alone. There was no evidence that aspirin treatment reduced mortality. There was no significant difference in the primary endpoint of 28-day mortality (17% aspirin vs. 17% usual care; rate ratio 0.96 [95% confidence interval 0.89-1.04]; p=0.35). The results were consistent in all pre-specified subgroups of patients.

Patients allocated to aspirin had a slightly shorter duration of hospitalisation (median 8 days vs. 9 days) and a higher proportion were discharged from hospital alive within 28 days (75% vs. 74%; rate ratio 1.06; 95% CI 1.02-1.10; p=0.0062). Among those not on invasive mechanical ventilation at baseline, there was no significant difference in the proportion who progressed to invasive mechanical ventilation or death (21% vs. 22%; risk ratio 0.96; 95% CI 0.90-1.03; p=0.23). For every 1000 patients treated with aspirin, approximately 6 more patients experienced a major bleeding event and approximately 6 fewer experienced a thromboembolic (clotting) event.

<u>Peter Horby</u>, Professor of Emerging Infectious Diseases in the Nuffield Department of Medicine, University of Oxford, and Joint Chief Investigator for the RECOVERY trial, said: 'The data show that in patients hospitalised with COVID-19, aspirin was not associated with reductions in 28-day mortality or in the risk of progressing to invasive mechanical ventilation or death. Although aspirin was associated with a small increase in the likelihood of being discharged alive this does not seem to be sufficient to justify its widespread use for patients hospitalised with COVID-19.'

<u>Martin Landray</u>, Professor of Medicine and Epidemiology at the Nuffield Department of Population Health, University of Oxford, and Joint Chief Investigator, said 'There has been a strong suggestion that blood clotting may be responsible for deteriorating lung function and death in patients with severe COVID-19. Aspirin is inexpensive and widely used in other diseases to reduce the risk of blood clots so it is disappointing that it did not have a major impact for these patients. This is why large randomised trials are so important – to establish which treatments work and which do not. As ever, we are enormously grateful to the thousands of medical staff and patients who have contributed to the RECOVERY trial, helping to find better treatments for patients all around the world.'

The results of this evaluation of aspirin have been published today on <u>medRxiv</u> and have been submitted to a leading peer-reviewed medical journal.

Notes

For further information or interviews with the chief investigators, please contact Dr Caroline Wood, <u>caroline.wood@ndph.ox.ac.uk</u>.

Full details of the study protocol and related materials are available at www.recoverytrial.net.

The RECOVERY trial is conducted by the registered clinical trials units with the Nuffield Department of Population Health in partnership with the Nuffield Department of Medicine. The trial is supported by a grant to the University of Oxford from UK Research and Innovation/National Institute for Health Research (NIHR) and by core funding provided by the NIHR Oxford Biomedical Research Centre, Wellcome, the Bill and Melinda Gates Foundation, the Foreign, Commonwealth & Development Office, Health Data Research UK, the Medical Research Council Population Health Research Unit, and NIHR Clinical Trials Unit Support Funding. Funding for RECOVERY International is provided by Wellcome through the COVID-19 Therapeutics Accelerator.

The RECOVERY trial currently involves many thousands of doctors, nurses, pharmacists, and research administrators at 177 hospitals across the whole of the UK, two hospitals in Nepal, and two hospitals in Indonesia. In the UK, the trial is supported by staff at the NIHR Clinical Research Network, NHS DigiTrials, Public Health England, Department of Health & Social Care, the Intensive Care National Audit & Research Centre, Public Health Scotland, the Secure Anonymised Information Linkage at the University of Swansea, and the NHS in England, Scotland, Wales and Northern Ireland.