RECOVERY trial closes recruitment to colchicine treatment for patients hospitalised with COVID-19

Statement from the RECOVERY trial chief investigators, 5 March 2021

The RECOVERY trial was established as a randomised clinical trial to test a range of potential treatments for COVID-19. Since November 2020, the RECOVERY trial has included a randomised comparison of colchicine vs. usual care alone. Colchicine is an anti-inflammatory drug that is commonly used to treat gout and which has been suggested as a treatment for COVID-19. To date there has been no convincing evidence of the effect of colchicine on clinical outcomes in patients admitted to hospital with COVID-19.

The RECOVERY trial independent Data Monitoring Committee (DMC) held a routine meeting on Thursday 4 March to review the available safety and efficacy data.

On the advice of the DMC, recruitment to the colchicine arm of the RECOVERY trial has now closed. The DMC saw no convincing evidence that further recruitment would provide conclusive proof of worthwhile mortality benefit either overall or in any pre-specified subgroup.

The DMC reviewed data on patients randomised to colchicine vs. usual care alone. The preliminary analysis is based on 2178 reported deaths among 11,162 randomised patients, 94% of whom were being treated with a corticosteroid such as dexamethasone. There is no significant difference in the primary endpoint of 28-day mortality (20% colchicine vs. 19% usual care alone; risk ratio 1.02 [95% confidence interval 0.94-1.11]; p=0.63). Follow-up of patients is ongoing and final results will be published as soon as possible.

Recruitment to all other treatment arms – aspirin, baricitinib, Regeneron's antibody cocktail, and (in selected hospitals) dimethyl fumarate – continues as planned.

Martin Landray, Professor of Medicine and Epidemiology at the Nuffield Department of Population Health, University of Oxford, and Joint Chief Investigator, said 'The RECOVERY trial has already identified two anti-inflammatory drugs – dexamethasone and tocilizumab – that improve the chances of survival for patients with severe COVID-19. So, it is disappointing that colchicine, which is widely used to treat gout and other inflammatory conditions, has no effect in these patients. We do large randomised trials to establish whether a drug that seems promising in theory has real benefits for patients in practice. Unfortunately, colchicine is not one of those.'

Peter Horby, Professor of Emerging Infectious Diseases in the Nuffield Department of Medicine, University of Oxford, and Joint Chief Investigator for the RECOVERY trial, said 'This is the largest ever trial of colchicine and it was only possible thanks to the hard work of NHS staff and the huge contribution made by patients across the whole country. Whilst we are disappointed that the overall result is negative, it is still important information for the future care of patients in the UK and worldwide.'

Notes

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

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 within the Nuffield Department of Population Health in partnership with the Nuffield Department of Medicine. The trial is supported by grants to the University of Oxford from the National Institute for Health Research (NIHR), UK Research and Innovation, and Wellcome, and by core funding provided by the Bill and Melinda Gates Foundation, the Foreign, Commonwealth & Development Office, Health Data Research UK, the Medical Research Council Population Health Research Unit, NIHR Clinical Trials Unit Support Funding, the NIHR Oxford Biomedical Research Centre, and Wellcome.

The RECOVERY trial currently involves many thousands of doctors, nurses, pharmacists, and research administrators at 177 hospitals across the whole of the UK, and hospitals in Nepal, and 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.