RECOVERY trial investigators

5 March 2021

Dear Colleagues

On the advice of the Data Monitoring Committee, recruitment to the colchicine arm has now been halted. Follow-up of all patients should continue.

The RECOVERY Data Monitoring Committee (DMC) reviewed data on patients randomised to colchicine vs. usual care at a routine meeting yesterday (4 March). 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).

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 therefore recommended that recruitment to the colchicine portion of the study should cease and follow-up be completed.

Actions:

- The colchicine arm has been removed from the randomisation system.
- Colchicine should no longer be administered as part of the trial (patients recently randomised should not be given any further doses).
- Follow-up should continue as usual: a follow-up form should be completed for all patients following death, discharge from hospital, or 28 days.

All other study arms continue as planned

As advised by the DMC, the recruitment of patients to all other treatment comparisons remains open.

We would like to thank you and all your colleagues for continuing to support the RECOVERY trial. You are making a huge difference to patient care both within the NHS and all around the world.

Yours sincerely

Peter Horby PhD FRCP Martin Landray PhD FRCP

Chief Investigators for the RECOVERY trial

Attached: RECOVERY DMC letter 4 March 2021

The University of Edinburgh
Edinburgh Neuroscience

CCBS
Centre for Clinical Brain Sciences

Professor Peter Horby, Professor Martin Landray
RECOVERY trial Co-chairs
Nuffield Department of Population Health
Oxford

4th March 2021

Dear Peter and Martin

RECOVERY trial DMC report

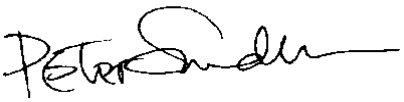
The RECOVERY trial DMC reviewed the safety and efficacy data that were available today for the 38,233 patients randomised (including 237 children and 100 women who were pregnant at entry). For the interventions still in active recruitment, the numbers included in the comparison of each agent with its control were respectively: REGN-COV2 (9,001), aspirin (14,167), colchicine (11,162) and baricitinib (2,153).

For colchicine, we saw no convincing evidence that further recruitment would provide conclusive proof of worthwhile mortality benefit either overall or in any pre-specified subgroup. We therefore recommend that recruitment to the colchicine portion of the study should cease and follow-up be completed.

For all the other treatments under study in RECOVERY, in the light of the available trial data and all relevant external information, we saw no cogent reason to modify the protocol or intake to the study.

The DMC will next review the safety and efficacy data for all treatments on 18th March 2021.

Yours sincerely



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Cc DMC members, RECOVERY trial office.

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