RECOVERY trial finds that dimethyl fumarate does not improve recovery for patients hospitalised with COVID-19

The Randomised Evaluation of COVID-19 Therapy (RECOVERY) trial has demonstrated that the anti-inflammatory drug dimethyl fumarate (DMF) does not improve clinical outcomes for patients hospitalised with COVID-19. The results have been published today on medRxiv.

DMF is an anti-inflammatory drug usually prescribed to treat multiple sclerosis and psoriasis. Because of its anti-inflammatory and possible anti-viral effects, the UK COVID-19 Therapeutics Advisory Panel recommended testing DMF in an initial assessment, which would have been followed by a larger trial had initial results been encouraging.

A total of 713 patients across 27 UK hospitals were included in the DMF evaluation with 356 randomly allocated to receive DMF plus usual care and 357 to usual care alone. 95% of patients were also receiving corticosteroids as part of their usual care. Participants who were allocated DMF received 120mg by mouth every 12 hours for the first four doses followed by 240mg every 12 hours for the total treatment duration of 10 days or until hospital discharge, whichever was sooner.

The primary outcome measure of the trial was disease severity at day 5, assessed using a seven-point scale. Treatment with DMF was not associated with an improvement in this measure compared with usual care alone (common odds ratio of unfavourable outcome in those treated with DMF 1.12; 95% CI 0.85-1.46; p=0.42).

DMF also had no significant effect on any secondary outcomes, including levels of blood oxygen, measures of a blood marker of inflammation, or time to discharge from hospital. DMF caused flushing and gastrointestinal symptoms, each in around 6% of patients, which are recognised side effects of treatment; no new side effects of DMF were identified.

Dr Leon Peto, Senior Clinical Research Fellow at Oxford Population Health, said ‘Dimethyl fumarate blocks a specific pathway by which inflammation can occur, which seemed to be involved in the lung damage caused by COVID-19. It was promising as a potential COVID-19 treatment, but unfortunately we have found that it does not provide any benefit in patients admitted to hospital. RECOVERY was the first trial of DMF, so this negative result helps us to understand more about what does drive lung damage in COVID-19, and focus on other treatments that may be effective.’

As an early phase study, the trial was not large enough to rule out a benefit in mortality, nor to assess whether treatment effects might have varied among specific groups of patients.

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