

Remdesivir and RECOVERY

Patients who are already receiving remdesivir **can still be** recruited into RECOVERY and receive any of the available study treatments (unless they have a separate contraindication to any of the RECOVERY study treatments).

Similarly, RECOVERY participants **can** receive remdesivir and continue their assigned treatment(s) in RECOVERY.

Information will be collected in RECOVERY on use of remdesivir at baseline and during the hospital stay.

If you have any further questions, please contact the study team.

Remdesivir and ACTT-1

Remdesivir is an inhibitor of the viral RNA polymerase which has shown *in vitro* efficacy against SARS-CoV-2 virus. The US National Institutes of Health-sponsored Adaptive COVID-19 Treatment Trial (ACTT-1) compared remdesivir with placebo among 1063 patients admitted to hospital with laboratory-confirmed SARS-CoV-2 infection and hypoxia (either receiving supplementary oxygen or oxygen saturations <94% on room air).

Mean age was 58.9 years and 64% were male. At baseline, 40% needed supplementary oxygen, 19% needed non-invasive ventilation and 26% were receiving invasive mechanical ventilation or ECMO. The primary outcome was time to recovery, where recovery was defined as discharge alive from hospital or remaining in hospital but not requiring oxygen or ongoing medical care (e.g. if hospitalisation prolonged for infection control reasons).

The Data and Safety Monitoring Board recommended the trial stop on 27 April 2020 at which point 731 participants had either met the primary outcome, died or passed 29 days post-randomisation. Preliminary results have since been published which demonstrate that participants assigned remdesivir had a shorter time to recovery: median 11 versus 15 days; rate ratio 1.32 (95% CI 1.12-1.55). Mortality at 14 days was numerically lower: 32 (7.1%) vs 54 (11.9%); HR 0.70 (95% CI 0.47-1.04).

MHRA EAMS

On 26 May 2020 the UK MHRA approved remdesivir for use in an Early Access to Medicines Scheme (EAMS). The criteria for access can be found <u>here</u>.

Implications for RECOVERY

The RECOVERY protocol does not exclude participants receiving other treatments for COVID-19. If one of the RECOVERY study treatments is known to interact with the patient's current treatment then that study treatment can be excluded from the randomisation for that patient, but they can still enter RECOVERY. However, Remdesivir has no known drug-drug interactions.