RECOVERY-RS

RESPIRATORY SUPPORT

TRIAL SUMMARY

Funder	National Institute of Health Research (NIHR)
Chief Investigators	Professor Gavin Perkins, University of Warwick & Professor Danny McAuley, Queen's University Belfast
Sponsor	University of Warwick
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Trial website	https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/

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Trial Title	RECOVERY-RS Respiratory Support: Respiratory Strategies in COVID-19; CPAP, High-flow, and standard care	
Urgent Public Health Trial	**RECOVERY-RS is listed as a priority UPH study:** **https://www.nihr.ac.uk/covid-studies/study-detail.htm?entryId=282338**	
Clinical Phase	Phase III	
Trial Design	Adaptive (group-sequential), pragmatic, randomised controlled, open-label, multi-centre, effectiveness trial	
Trial Participants	Adult, critically ill patients, with suspected or confirmed, COVID-19	
Planned sample size	4002	
Inclusion criteria	Adults ≥ 18 years; Admitted to hospital with suspected or proven COVID-19; FiO_2 ≥0.4 and SpO_2 ≤94%; Plan for escalation to intubation if needed.	
Exclusion criteria	Planned intubation and mechanical ventilation imminent within 1 hour; known or clinically apparent pregnancy; any absolute contraindication to CPAP of HFNO; Decision not to intubate due to ceiling of treatment or withdrawal of treatment anticipated; Equipment for both CPAP and HFNO not available.	
Interventions	Patients will be randomised to a 1:1:1 ratio (standard care: CPAP: HFNO). Patients in all three treatment groups will be intubated and receive invasive mechanical ventilation if clinically required. CPAP and HFNO will be administered according to local protocol/guidelines. Standard care will comprise regular ward level oxygen therapy according to local protocol/guidelines, and excludes escalation to CPAP and HFNO. If sites cannot, or do not wish to, provide one of the intervention arms (CPAP or HFNO), it is still possible to participate. In this situation, the randomisation system will only allocate either the standard care or the intervention arm which is provided at that site. (1:1 ratio standard care: CPAP **or** HFNO)	
Treatment Duration	Duration based on clinical discretion	
Follow-up Duration	30 days or hospital discharge, whichever comes latest	
Planned Trial Period	18 months including 12 months recruitment	
	Objectives	Outcome Measures
Primary	To determine if CPAP or HFNO is clinically effective compared to standard care (excluding CPAP or HFNO)	Tracheal intubation or mortality within 30-days
Secondary	To assess in-hospital patient data in terms of their stay	Intubation rates; time to intubation; time to death (mortality); mortality in critical care (Level 2/3); mortality in hospital stay; mortality at 30 days; length of stay in critical care (Level 2/3); length of stay in hospital