ULTIMATE Domain

Protocol Summary, dated: 13Jun2023
https://practicalplatform.org/domains/ultimate

Primary Objective	To determine the feasibility of recruiting 72 patients over 1 year of active enrolment, as well as assess the rate of participant recruitment and understand the barriers to enrolment.
Design	An interventional, open-label, randomized, multi-site feasibility study.
Eligible Patient States	Intubated patients with PaO_2/FiO_2 <200, not on ECLS, with high normalized respiratory system elastance (≥2.5 cm H_2O/(mL/kg predicted body weight))
Interventions	Participants will be randomized to receive either the experimental intervention: ultra-protective ventilation facilitated by an ECMO device or the control group: usual care, standard lung protective ventilation
Outcome	• Primary outcome is feasibility ○ Recruitment rate ○ Protocol Adherence ▪ $\Delta P_{L\text{-}dyn} \leq 20$ cm H_2O and V_T<8 ml/kg ○ Crossovers • Secondary outcomes ○ Complications ○ Clinical outcomes
Duration	The duration of this study will include an estimated 1 year of recruitment to reach target sample size, and 6 months of follow up.
Sample Size	Approximately 72 evaluable patients will be randomized in this domain protocol.