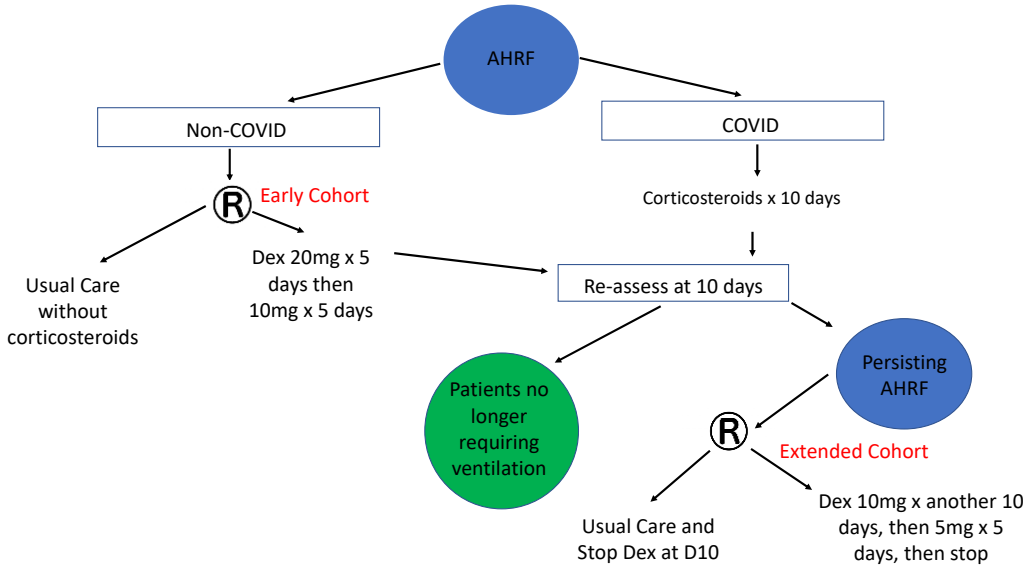
The Corticosteroid Early and Extended (CORT-E^2) Randomized Controlled Trial

Protocol Summary, dated: 22-Dec-2022

https://practicalplatform.org

Hypothesis	Early corticosteroids will improve survival (Early Cohort) in patients with non-COVID AHRF; and extending corticosteroids (Extended Cohort) will improve survival in those with AHRF still requiring invasive or non-invasive respiratory despite already receiving 10 days of corticosteroids.
Primary Outcome	60-day mortality from the day of randomization
Eligible Patient States	1. Non-intubated patients 2. Intubated patients, not on ECLS, with low normalized respiratory elastance (<2.5 cm H_2O/(mL/kg predicted body weight)) 3. Intubated patients, not on ECLS, with high normalized respiratory system elastance (≥2.5 cm H_2O/(mL/kg predicted body weight)) 4. Patients on ECLS
Design & Intervention	Multicentre Bayesian RCT, which includes two cohorts; early corticosteroids in non-COVID AHRF (**Early Cohort**) and extended corticosteroids in persisting AHRF due to COVID or non-COVID (**Extended Cohort**). Patients that enroll in the Early Cohort, may be eligible to randomize to the Extended Cohort after treatment as part of the Early Cohort. Dexamethasone will be sourced locally from each sites pharmacy. 
Duration	We will collect data on patients during the ICU and hospital stay. The only planned post-ICU discharge follow-up is for vital status (dead or alive) at 60 days and 6 months and for quality of life at 6 months. This will be assessed by monitoring available electronic medical records, obituaries and contacting the patient/family by telephone, if required.
Sample Size	The Bayesian approach does not require a fixed sample size as the trial will continue enrolling until a statistical trigger is met. It is estimated that a maximum of 2000 patients will be enrolled in each cohort at 30 to 40 sites.