REMAP-CAP
Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

REMAP-CAP: a platform trial for severely ill patients with COVID-19

Background

REMAP-CAP is a trial designed by clinicians who cared for patients and conducted research during the 2009 H1N1 pandemic. Planning began in 2011. REMAP-CAP is supported by multiple government grants.

REMAP-CAP builds on the combined input of the world's leading ICU trial networks and experts in infectious disease, immunology, critical care, emergency medicine, Bayesian statistics, and clinical trial execution. These existing networks have enrolled tens of thousands of patients into trials. They have extensive experience designing, conducting, and reporting clinical trials that enroll patients who are severely ill.

Objective

Our goal is to generate evidence that can be applied during the pandemic to *reduce mortality*, *reduce ICU use*, and *reduce morbidity* in severely ill patients with COVID-19 infection.

Designed for the pandemic

For the past several years, REMAP-CAP has been recruiting patients with severe CAP in the inter-pandemic period. We are currently recruiting in more than 50 ICUs in 13 countries on 3 continents. Another 50 ICUs are in start-up, and more countries and networks are being added daily. REMAP-CAP was designed to adapt to an acute pandemic need: that time has come. Changes necessary for the pandemic have been approved or submitted for approval and we are currently enrolling patients with COVID-19.

Designed to generate answers quickly

REMAP-CAP can recruit without dedicated research staff. The bedside clinician can enroll patients in minutes. The trial is a Bayesian adaptive platform trial, generating answers to many questions rapidly.

- The platform is multifactorial: each patient can be randomized to multiple treatments.
- It uses frequent interim analyses: a question is concluded as soon as there is sufficient information to support a conclusion. Analyses can occur every week.
- It detects superiority, inferiority, or equivalence of interventions within the platform.
- Additional interventions are added, as required, based on availability and external evidence.
- By assigning patients to 'recipes' of treatments, only a few patients receive no active therapy.

Current treatments

REMAP-CAP will study, on an open-label basis:

- Antiviral therapy (no antiviral, lopinavir/ritonavir (Kaletra), hydroxychloroquine being added)
- Corticosteroid strategy (no steroid, fixed 7 days, only while in septic shock)
- Immune modulation (no modulator, interferon-beta, anakinra, other agents being added)

The platform can evaluate interactions, e.g. do steroids work only when an active antiviral is administered. The platform can study ALL hospitalized patients (as is happening in the US) OR coordinate with other pre-ICU hospital-based trials (as is happening in Australia, New Zealand, Canada, and the UK).

Designed to be flexible

REMAP-CAP can co-enroll with other studies. Sites and regions can choose the domains and interventions from the 'menu' of current questions, and need not adopt all domains or interventions.

Designed to improve outcome for participants

The platform uses response adaptive randomization. After each interim analysis, the weighting of randomization is modified so that patients are more likely to receive those interventions that are preforming best.

more detail @ www.remapcap.org