



STOP-
COVID19 | Superiority Trial
Of Protease
inhibition in
COVID-19

Co-ordination of REMAP-CAP and STOP-COVID19 Trials

REMAP-CAP is a multi-centre international adaptive platform trial of critically ill patients with community acquired pneumonia, including COVID-19. It has multiple domains to evaluate multiple interventions simultaneously, which have included steroids, macrolides, antivirals and immunomodulators, and will also evaluate potential interactions

STOP-COVID19 is a UK randomized trial being conducted in 15 UK centres to test whether Brensocatib compared with placebo improves clinical outcomes and reduces mortality in COVID-19 patients admitted to hospital.

REMAP-CAP and STOP-COVID19 have agreed that:

- Patients transferred straight into ICU at a site where REMAP-CAP is active will be approached for enrolment into REMAP-CAP
- Patients transferred straight into ICU at a site where REMAP-CAP is not active can be approached for enrolment in STOP-COVID19
- If a patient is already randomised into STOP-COVID19 is transferred to an ICU where REMAP-CAP is active, the patient may be co-enrolled in REMAP-CAP and where possible should continue to receive their randomized intervention in STOP-COVID19. All randomization options for REMAP-CAP, **except for lopinavir/ritonavir** are available for participants previously randomized to STOP-COVID19.
- RECOVERY and STOP-COVID19 will work closely together to share information on participating sites, interventions, and co-enrolments.

Current domains active in the REMAP-CAP Trial:

Pandemic interventions are:

Antivirals: Lopinovir /Ritonavir / No antiviral against COVID-19

There is a known negative drug interaction between Brensocatib and Lopinovir /Ritonavir. Patients randomised into STOP-COVID19 cannot be randomised into the COVID-19 Antiviral domain.

Immune modulators: Tocilizumab / Sarilumab / interferon / anakinra / No immune modulators against COVID-19

Immunoglobulin: Convalescent Plasma / No convalescent plasma

Anticoagulation: local venous thrombopropylaxis / therapeutic anticoagulation

Statins: Simvastatin / No statins

Vitamin C: Vitamin C / No Vitamin C

REMAP-CAP Pandemic patients can also be randomised to **non-pandemic specific domains** if eligible:

Antibiotics and Macrolides:

Ceftriaxone + Macrolide

Moxifloxacin or Levofloxacin

Piperacillin-tazobactam + Macrolide

Ceftaroline + Macrolide

Amoxicillin-clavulanate + Macrolide

Corticosteroids: No steroid / fixed duration hydrocortisone / hydrocortisone only in septic shock

Influenza Antivirals: oseltamivir / no oseltamivir

Patients can be co-enrolled in both STOP-COVID19 and REMAP-CAP, however because of a known negative drug interaction between Lopinovir/Ritonavir and Brensocatib. These patients should not be randomised into the COVID-19 antiviral domain of REAMP-CAP.

2nd September 2020