RECOVERY
Randomised Evaluation of COVID-19 Therapy

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

Coordination of RECOVERY and REMAP-CAP trials

RECOVERY is a large-scale randomised trial open to every NHS Trust in the UK. Any COVID-19 patient in hospital in the UK may be invited to participate. RECOVERY is focussed on evaluating drugs that are available in sufficient volume to enrol a large number of patients and assess the impact of the drug on the risk of death. In adult patients the current interventions being investigated include azithromycin, tocilizumab, convalescent plasma, monoclonal antibodies against coronavirus and aspirin.

REMAP-CAP is a multi-centre international adaptive platform trial of severely ill adult patients with community acquired pneumonia, including COVID-19. It has multiple domains to evaluate multiple interventions simultaneously, including macrolides, antivirals, immunomodulators, immunoglobulins (convalescent plasma), anti-coagulants, anti-platelet drugs, statins (simvastatin) and high dose vitamin C and will also evaluate potential interactions.

RECOVERY and REMAP-CAP have agreed that:

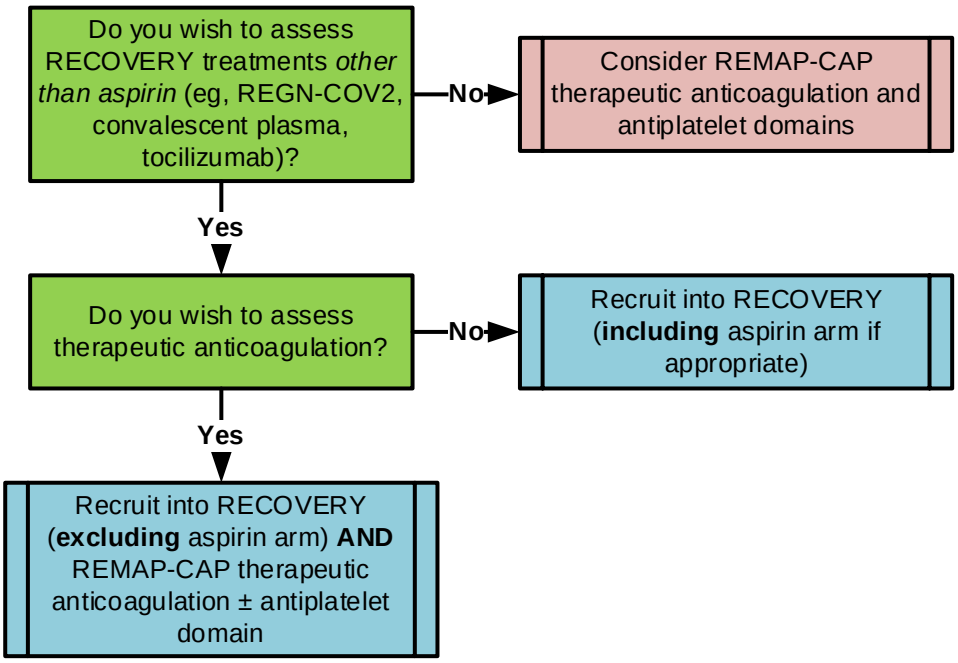
- RECOVERY and REMAP-CAP will work closely together to ensure that the most promising investigational products are evaluated in the most appropriate trial for the target patient group. This will ensure we answer the important clinical questions quickly, efficiently and across the whole disease spectrum.
- 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 will be approached for enrolment in RECOVERY.
- If a patient randomised to an intervention through RECOVERY on the ward is then subsequently transferred to an ICU where REMAP-CAP is active, the patient may be co-enrolled in REMAP-CAP but will not be changed from the active intervention they were allocated in RECOVERY. The modular nature of the REMAP-CAP protocol allows randomisation in specific domains. Details for RECOVERY participants are given below.
- If a patient is allocated to azithromycin in RECOVERY, they would be excluded from the REMAP-CAP macrolide domain, as this treatment would continue. However, if they are not allocated to azithromycin in RECOVERY, then they could be considered for entry into the macrolide domain in REMAP-CAP, if judged clinically appropriate.
- If a patient is allocated to tocilizumab in RECOVERY, they would be excluded from the REMAP-CAP immune modulation domain. However, if they are not allocated to tocilizumab in RECOVERY, then they could be considered for entry into the immune modulation domain in REMAP-CAP, if judged clinically appropriate.
- If a patient is allocated to convalescent plasma or monoclonal antibodies in RECOVERY, they would be excluded from the REMAP-CAP immunoglobulin domain. However, if they are not allocated to convalescent plasma or monoclonal antibodies in RECOVERY, then they could be considered for entry into the immunoglobulin domain in REMAP-CAP, if judged clinically appropriate.

- If a patient is allocated to aspirin in RECOVERY, they would be excluded from the anti-platelet domain in REMAP-CAP (but see below if also enrolling into REMAP-CAP outside ICU). However, if they are not allocated to aspirin in RECOVERY, then they could be considered for entry into the antiplatelet domain in REMAP-CAP in ICU, if judged clinically appropriate.

NOTE: This co-enrolment strategy should only be considered if patients have been included in RECOVERY on the ward and then deteriorate clinically to require ICU admission.

- If a patient has been randomised in the REMAP-CAP macrolide domain, immune modulation domain, immunoglobulin domain or the antiplatelet domain in ICU they should not be subsequently randomised in RECOVERY. Similarly if a patient has been randomised in RECOVERY when already admitted to ICU they should not be randomised to these domains in REMAP-CAP.
- RECOVERY and REMAP-CAP will work closely together to share information on participating sites, interventions, and co-enrolments.

For sites enrolling into REMAP-CAP outside ICU:



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