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

13 July, 2020

Dear REMAP-CAP sites,

**RE: Hydroxychloroquine Interventions and Corticosteroid Domain in REMAP-CAP**

I am writing to inform you of a number of decisions that have been made by the REMAP-CAP international trial steering committee (ITSC) in response to the results publicised from the RECOVERY trial, plus feedback from sites and regulatory bodies.

Hydroxychloroquine

The ITSC have decided to permanently close the hydroxychloroquine-containing interventions of the COVID-19 Antiviral Domain. These interventions have already been discontinued at all sites participating in REMAP-CAP.

While the results of the RECOVERY trial have to date only been made available as a press release, the dissemination of these results has resulted in a loss of clinical equipoise globally. The ITSC felt that even if these interventions were to remain open, it is unlikely that significant numbers of patients would be randomised to them.

Our intention is to consult with the DSMB to close these interventions and to report the data that is available to us relating to hydroxychloroquine-containing interventions. In this way the limited data generated by REMAP-CAP may still be used to inform clinical decision making.

Lopinavir/ritonavir

On the 29th of June, the RECOVERY trial issued a press-release which includes results relating to their lopinavir/ritonavir intervention. Importantly, only approximately 4% of the patients included in this arm were receiving invasive ventilation at randomisation. Given the potentially important differences between the patient population in RECOVERY and REMAP-CAP, the ITSC have decided to continue this intervention pending further evidence becoming available.

Remdesivir

As you will be aware remdesivir is becoming licensed for COVID-19 in many locations. The view of the ITSC is that the quality of evidence supporting improved patient-centered outcomes for patients who are critically ill is limited, at this time. The ITSC is interested in the possibility of introducing remdesivir into the REMAP-CAP platform but, if this was done, it is intended that sites that wish to administer remdesivir to all patients would be able to do so. No decision regarding remdesivir in the platform has been made and is also dependent on availability of remdesivir for use within a trial. The COVID-19 antiviral DSA will be amended to permit off-trial remdesivir use.

Corticosteroids

As many of you will be aware, recruitment of patients with proven or suspected COVID-19 to the corticosteroid domain of REMAP-CAP has been paused since the release of results from the RECOVERY trial on the 16th June. The ITSC have now decided to permanently close recruitment to this domain

for patients with proven or suspected pandemic infection, and to analyse and report our results. Note that this domain will continue to be available for patients with community-acquired pneumonia who do not have proven or suspected COVID-19.

The ITSC have been approached by the WHO to contribute to a meta-analysis of currently-running trials evaluating steroids in critically ill patients with COVID-19. It is our intention to contribute to this important publication, and also to publish a standalone manuscript of REMAP-CAP data relating to the use of corticosteroids for patients with proven or suspected COVID-19.

If you have any questions about any of the above, please don't hesitate to contact me.

Sincerely,

Professor Steve Webb
Chair,
REMAP-CAP International Trial Steering Committee

Phone: +61 408 866 274
Email: Steven.Webb@monash.edu