MEDIA RELEASE

UNDER EMBARGO UNTIL:
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Arthritis drug effective in treating sickest COVID-19 patients

Critically ill patients with COVID-19 treated with a drug that reduces inflammation by modifying the immune system have improved outcomes, an international study has found.

The early findings, which are yet to be published, come from the REMAP-CAP trial. Monash University is the global coordinating centre for the trial which has been supported by Minderoo Foundation and the National Health and Medical Research Council.

The trial evaluates the effect of treatments on a combination of survival and length of time patients need support in an ICU. The results show that treatment with the immune modulator tocilizumab met this efficacy end-point among critically ill patients with severe COVID-19, compared to patients who did not receive any immune modulation treatment. The relative contribution of survival and reduced length of time needing organ support in ICU has not yet been analysed.

Due to the clinical implications for patients, the researchers have released the findings before they have been peer-reviewed, but are working to analyse and publish the full results as soon as possible.

Prof. Steve Webb, intensive care specialist and Professor of Critical Care Research at Monash University, who is the Chair of the trial's international steering committee said: "These early findings show that treatment with this immune modulating drug is effective for critically ill COVID-19 patients in intensive care units. When we have the results available from all participants, we hope our findings will offer clear guidance to clinicians for improving the outcomes of the sickest COVID-19 patients."

The latest analysis was carried out by a Statistical Analysis Committee separate from the trial investigators and reviewed by an independent Data and Safety Monitoring Board (DSMB) on 17th November. The analysis included data from the first 303 patients randomized to receive immune modulation treatments: tocilizumab, sarilumab, anakinra, interferon, or no immune modulator.

Patients receiving tocilizumab were more likely to improve (measured by a combination of organ support in the ICU and surviving the hospital admission) compared to patients who

received no immune modulator. However, the trial does not yet know the relative benefits of tocilizumab compared to the other immune modulators. Further data are expected in the coming weeks and months.

The trial data yielded an estimated odds ratio of 1.87 for a better outcome with tocilizumab compared to no immune modulation, with a high degree of statistical certainty (99.75% probability that tocilizumab is superior to no immune modulation).

In addition to these findings, the latest analysis also revealed an antiviral drug called Kaletra (lopinavir/ritonavir) to be ineffective and provide no additional benefit to critically ill COVID-19 patients, compared to those who did not receive the drug. The analysis found an estimated odds-ratio of 0.67 (worse than control) with a 99.9 per cent probability of futility (an odds ratio less than 1.20).

REMAP-CAP began investigating treatments for COVID-19 in March 2020, enrolling hospitalised patients with either moderate or severe (requiring ICU care) COVID-19 disease.

The study design randomises patients to multiple combinations of treatments, enabling researchers to evaluate different treatments for COVID-19, including antivirals, drugs which modulate the immune response, and therapies that modulate or support other vital aspects of the body's response to the virus.

In total, over 2,000 patients in 15 countries have been enrolled at more than 260 hospitals worldwide and randomized to multiple treatment combinations. The effects of interventions are assessed separately for moderate and severely ill patients.

The latest findings on tocilizumab and lopinavir/ritonavir add to REMAP-CAP findings from earlier this year, which found that hydrocortisone steroid treatment improved recovery among critically ill COVID-19 patients.

“This is an absolutely amazing result”, said Dr. Lennie Derde, Consultant in Intensive Care Medicine at the University Medical Center in Utrecht, the sponsor of the study in Europe, and the Immune Modulation Domain Specific Working Group Chair. “To have a second effective therapy for critically ill patients within months of the start of the pandemic is unprecedented. Specific targeting of the immune response is theoretically attractive, and now we have shown it works”.

In May 2020, Minderoo Foundation provided $2 million funding to expand the COVID-19 arms of the ongoing REMAP-CAP study. This included facilitating expansion into low-socioeconomic areas including Pakistan, Nepal and India, enrichening the data and providing access to the study’s novel treatments in those areas.

Dr Steve Burnell who leads Minderoo Foundation's COVID-19 response said:

"Minderoo is proud to support REMAP-CAP. These latest findings on Tocilizumab represent the second effective therapy for patients with serious COVID-19 that this global trial has identified in the last few months. REMAP-CAP's agility and flexibility are what makes it so innovative, its design enables researchers to collaborate, test and share data quickly.

"Australia is fortunate to currently have so few COVID-19 cases, but the pandemic continues to have a devastating impact in many countries. These latest results will ensure more critically ill patients around the world receive the life-saving treatments they need and, importantly, avoid treatments that do not help."

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Prof Steve Webb is available to speak to media under embargo until 22:45 AEDT 19 November 2020, and again from 09:30 AEDT 20 November 2020

REMAP-CAP
REMAP-CAP (The Randomized Embedded Multifactorial Adaptive Platform for Community Acquired Pneumonia) is an ongoing adaptive clinical trial involving more than 2000 COVID-19 patients at more than 260 clinical sites around the world, including 11 within New Zealand.

REMAP-CAP continues to evaluate multiple other treatments, including therapeutic anticoagulation, antiplatelet agents, apremilast, eritoran, anakinra, sarilumab, vitamin C, simvastatin, convalescent plasma, macrolides, and antibiotics.