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Media release

Thursday, 25 February, 2021

AustralaSian COVID-19 Trial opens in India

The AustralaSian COVID-19 Trial (ASCOT) has been expanded into India, with the first patients recruited last week to the first two sites, Christian Medical College and Hospital Ludhiana in Punjab and Sterling Multispecialty Hospital in Pune, Maharashtra.

ASCOT aims to discover which existing treatments are most effective in patients hospitalised with COVID-19 and whether they will prevent patients deteriorating to the point of needing a ventilator in the Intensive Care Unit.

ASCOT has partnered with the George Institute for Global Health to oversee the trial in India given its substantial experience operating clinical trials in the country with a presence in 21 states.

ASCOT Principal Investigator, Associate Professor Steven Tong, a Royal Melbourne Hospital infectious diseases clinician and co-lead of clinical research at the Doherty Institute said that while ASCOT began as an Australian and New Zealand trial, expanding internationally to allow more widespread access to investigational treatments was crucial.

"A key principle of the trial is equity in terms of access to experimental treatments that could potentially have benefits for patients," Associate Professor Tong said.

"The ASCOT Management Team and Leadership Group recognised early in the course of the trial that in order for it to have generalisability, external validity and be adequately powered, it would need to be expanded to international sites."

India, like many other middle and low-income countries, is facing a severe epidemic of COVID-19. The number of patients with COVID-19 in India remains significantly higher than in Australia and New Zealand, and access to experimental treatments is limited.

Bala Venkatesh, Professorial Fellow at the George Institute for Global Health, said that while there are other ongoing clinical trials in India for COVID-19, the novel combinations of treatments included in ASCOT will provide greater opportunities to patients for accessing new treatments.

"We are confident that the study questions being asked are of priority to Indian patients and participating trial sites, and feasible to address in India," said Professor Venkatesh.

One new treatment that's recently been added to ASCOT is nafamostat, which in laboratory experiments has shown to block SARS-COV-2 from entering human cells and be far more potent than remdesivir.

"Nafamostat is mainly used in Korea and Japan as a treatment for acute pancreatitis and some blood clotting conditions. Of all drugs with potency data from laboratory studies using human cell lines, nafamostat appears to be the most potent against SARS-CoV-2 and may be the only drug where blood concentrations almost always exceed levels required to stop the virus from replicating," explained Associate Professor Tong.







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"It is also likely that nafamostat will reach high levels in the lungs where the SARS-CoV-2 virus causes so much of its problems. What's more, it has a favourable safety profile."

The ASCOT Steering Committee recently made the decision to cease enrolment into the convalescent plasma arm of the trial following a media release issued by the UK's RECOVERY trial, which reported no benefit to patients compared with standard of care.

The ASCOT team would like to thank funders - Royal Brisbane and Women's Hospital Foundation, Pratt Foundation, Minderoo Foundation, BHP Foundation, Health Research Council of New Zealand, Hospital Research Foundation, Wesley Medical Research, Australian Partnership for Preparedness Research on Infectious Disease Emergencies (APPRISE), Macquarie Group Foundation and The Common Good (The Prince Charles Hospital Foundation).

Associate Professor Steven Tong and Professor Bala Venkatesh are available for interview at a virtual media conference at 10:30am (AEST) – Thursday, 25 February. Please register for the ZOOM MEDIA CONFERENCE via the link below:

https://unimelb.zoom.us/webinar/register/WN_mfUImRy4QFSjLmGHadVHIQ

After registering, you will receive a confirmation email containing information about joining the webinar. A recording will be available shortly after the conclusion of the press conference. Send an email to <u>rebecca.elliott@unimelb.edu.au</u> to be sent a link to download.

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About the AustralaSian COVID-19 Trial (ASCOT)

ASCOT is a clinical trial that will generate clinical evidence about treatment for COVID-19 that can be applied during the pandemic to reduce mortality or the need for mechanical ventilation in hospitalised but not yet critically ill patients with COVID-19. The trial aims to generate results quickly. After the trial begins, results will be continually analysed, so that ineffective therapies can be stopped and new therapies can be evaluated as part of the trial.

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About the Peter Doherty Institute for Infection and Immunity

Finding solutions to prevent, treat and cure infectious diseases and understanding the complexities of the immune system requires innovative approaches and concentrated effort. This is why The University of Melbourne – a world leader in education, teaching and research excellence – and The Royal Melbourne Hospital – an internationally renowned institution providing outstanding care, treatment and medical research – have partnered to create the Peter Doherty Institute for Infection and Immunity (Doherty Institute); a centre of excellence where leading scientists and clinicians collaborate to improve human health globally.

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