

Positives in first published clinical trial of COVID-19 treatment

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Summary: A statistician who worked on the first published large randomized clinical trial for a potential treatment for the COVID-19 virus said the study produced positive results.

FULL STORY

A Lancaster University statistician who worked on the first published large randomised clinical trial for a potential treatment for the COVID-19 virus said the scientific community was coming together to combat the coronavirus.

There are currently no specific treatments for COVID-19. However, it is possible that some existing drugs, usually used for other conditions, may have some benefits.

Professor Thomas Jaki, from the Medical and Pharmaceutical Statistics Research Unit in the Department of Mathematics and Statistics at Lancaster University, said the initial trial investigated whether anti-viral drugs used to treat HIV would relieve the symptoms of COVID-19 -- and started when there were less than 500 confirmed cases worldwide.

The trial saw 199 COVID-19 patients at Jin Yin-Tan Hospital treated either using standard of care or being given lopinavir-ritonavir. The results were published recently and showed enough promise that further, larger trials of the lopinavir-ritonavir treatment have now been established.

Specifically, the trial showed that patients who were randomly chosen to receive lopinavir-ritonavir appeared to improve faster. Meanwhile, among those patients who actually received lopinavir-ritonavir, the time to clinical improvement was significantly shorter than in patients receiving standard of care alone. At the same time acceptable safety levels were observed.

Professor Jaki said: "The results were quite encouraging, which has led to further studies taking place and I would expect to see these treatments to be introduced into routine care, in some cases, in the coming weeks."

The findings from this study will also be considered as part of the forthcoming Randomised Evaluation of COVid-19 thERapY (RECOVERY) trial. This will provide a trial platform to evaluate some of the approximately 30 treatments which are currently believed to have potential for treatment of COVID-19. The chief investigator for that trial is Peter Horby, Professor of Emerging Infectious Diseases and Global Health in the Nuffield Department of Medicine at the University of Oxford -- who was also part of the initial study in Wuhan.

Professor Jaki said the fact these studies were taking place during a medical emergency had seen a determination to move things forward at pace.

He added: "The astonishing thing about the RECOVERY trial is the speed with which it got off the ground, from the initial agreement being received from the Department of Health and Social Care it was just nine days before the first patient was recruited. That process would usually take between six and nine months.

"We have benefitted by learning from trials in China -- keep it simple. RECOVERY uses a very short protocol and attempts to minimise burden on staff in hospitals which are overwhelmed, so we have tried to ensure data collection is simple. It is an important study and one which needs to be done quickly.

"This is one of the largest trials into treatments for COVID-19. There is a second large trial that is currently recruiting in the UK -- REMAP-CAP -- which is looking at impacts of treatments on severely ill patients, but both teams have worked together to ensure they will be able to learn as much as they can from both trials.

"This is unusual but a lot of the competitive nature of these things isn't there at the moment. We all have the same goal."

The RECOVERY trial has been classed as an Urgent Public Health Research Study. It is one of a round of projects to receive £10.5m as part of the £20m rapid research response funded by UK Research and Innovation, and by the Department of Health and Social Care through the National Institute for Health Research (NIHR).

Chief Medical Officer Professor Chris Whitty and NHS England Medical Director Professor Stephen Powis have written to NHS trusts in England asking them to fully support the new trial.

Professor Jaki is also one of the authors of an opinion piece published in the *New England Journal of Medicine* last week on an approach to clinical trials around large epidemics.

While the piece was predominantly written months before the coronavirus outbreak, it encourages greater collaboration between scientists and much of the advice is already being reflected in the World Health Organisation's developing strategy.

Professor Jaki added: "This is the culmination of a conversation which started several years ago where the WHO recognised the necessity of pre-planning in the event of a disease outbreak.

"While it may sometimes feel like we are unprepared for incidents like the COVID-19 outbreak there is actually a co-ordinated global effort among scientists, and Lancaster plays its part in that."

Story Source:

Materials provided by **Lancaster University**. *Note: Content may be edited for style and length.*

Journal Reference:

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