

Press Release

Friday 16 June 2023

PROTECT-V study stepped up in fight against COVID

An international study led by Addenbrooke's Hospital will continue with its search to find drugs that protect the most vulnerable patients from Covid, many of whom have a weaker response to vaccination.

The reassurance came from Dr Rona Smith on Friday (16 June) after a two year study found a nasal spray, derived from niclosamide tablets originally used to treat tapeworm, does not prevent infection in vulnerable kidney patients.

Dr Smith, who was speaking to Europe's largest annual gathering of renal experts in Italy on Friday, explained that while the outcome was disappointing, there were still many important positives.

She told members of the European Renal Association gathered at Milan Conference Centre that the study "platform", called PROTECT-V, has proven so efficient the "framework" is already being used to test other drugs.

Sotrovimab, a drug developed by GSK/Vir has been shown to be an effective treatment for certain patients with COVID-19, and is now being tested as a preventative strategy.

The trial - which has attracted further funding from organisations including the life sciences charity LifeArc and Addenbrooke's Charitable Trust (ACT) - has expanded to include even more vulnerable patients.

In addition to individuals with kidney problems, those receiving drugs that suppress the immune system due to an organ transplant or an autoimmune disease, receiving cancer treatment, or with immunodeficiency, are eligible to join the next part of the study.

Dr Smith thanked all those involved in work so far and looked forward to maintaining and developing future partnerships.

She praised the support of University of Cambridge, Addenbrooke's Charitable Trust, Cambridge Clinical Trial Unit, NIHR Cambridge Biomedical Research Centre, The George Institute of Global Health in India, LifeArc, Kidney Research UK, UNION therapeutics, the Danish company that developed the niclosamide spray, and GSK/Vir which is supporting the sotrovimab arm.

She said: "The trial graphically illustrates the strength of international collaboration between charity, industry and academia, and successfully included vulnerable patients, who are often excluded from such trials.

"The trial of intranasal niclosamide was the largest pre-exposure prophylaxis study of a re-purposed agent conducted globally with 1,653 patients (1,233 from the UK and 420 from India) randomised to either receive niclosamide or placebo for up to 36 weeks.

"We have proven that the platform design brings efficiencies meaning other agents can be evaluated in same framework."

Executive director of research and policy at Kidney Research UK, Dr Aisling McMahon, added: "Dr Smith and her colleagues have demonstrated the feasibility of conducting an international randomised clinical trial in at-risk renal patients, with partners including the charity sector, NHS and pharmaceutical companies. We will continue to work to ensure that renal patients are well-represented in clinical studies and look forward to future results from the PROTECT-V platform study."

Chief Scientific Officer of UNION therapeutics Morten Sommer, said: "We are pleased to have been part of the PROTECT-V platform study and are grateful for the commitment and dedication of patients, caregivers, investigators and funders who all have been instrumental in a very well-conducted study. The mechanistic rationale was sound, so we are of course disappointed that the study did not meet its primary endpoint."

Addenbrooke's Charitable Trust chief executive, Shelly Thake, added: "ACT is proud to support the world-leading research taking place across Addenbrooke's, and we were delighted that our supporters' donations have contributed to a study which has sowed the seeds for more important work in the fight against COVID-19. While COVID is not the headline news it was, it can still have devastating consequences, particularly for the vulnerable."

LifeArc and The George Institute of Global Health in India said they were delighted to support PROTECT-V.

Dr Kovilen Sawmynaden, Senior Principal Scientist at LifeArc said: “LifeArc is committed to helping take scientific ideas out of the lab and into medical breakthroughs for patients, especially where there is an unmet medical need.

“To date, we have provided more than £27 million to fund the search for new medicines and diagnostics to address Covid-19 and we were delighted to support this study for a high-risk patient group facing a real unmet need.

“We are pleased that this funding has helped establish a platform study like PROTECT-V, that will continue to deliver new insights and now focus on other agents – including antibodies - which could be effective in helping prevent infection in high-risk patient groups.”

Professor Vivekanand Jha of the George Institute added: “The PROTECT-V trial is a collaborative endeavor between India and the United Kingdom. The inclusion of the Indian participants in this study amplifies the global reach of this research effort and provides the basis for important conclusions to be drawn. Our collective efforts in India and the United Kingdom, together with the participation of vulnerable renal patients, mark a crucial step forward in our pursuit of preventive treatment against SARS-CoV2 infection”.

Anyone who wants to learn more about PROTECT-V and the opportunities to get involved should visit https://www.camcovidtrials.net/trials/view,protect_50.htm.

-ENDS-

Note to editors: Pictured is Dr Rona Smith



About Cambridge University Hospitals

Cambridge University Hospitals NHS Foundation Trust (CUH) is one of the largest and best known trusts in the country, delivering high-quality patient care through Addenbrooke's and the Rosie Hospitals. CUH is a leading national centre for specialist treatment for rare or complex conditions and a university teaching hospital with a worldwide reputation.

CUH is a key partner in Cambridge University Health Partners (CUHP), one of only eight academic health science centres in the UK, and is at the heart of the development of the Cambridge Biomedical Campus (CBC), which brings together on one site a range of organisations involved in world-class biomedical research, patient care and education. The Campus hosts the National Institute for Health and Care Research (NIHR) Cambridge Biomedical Research Centre.

About LifeArc

LifeArc is a self-funded, not-for-profit medical research organisation. We take science ideas out of the lab and help turn them into medical breakthroughs that can be life-changing for patients. We have been doing this for more than 25 years and our work has resulted in five licensed medicines, including cancer drug pembrolizumab, and a diagnostic for antibiotic resistance.

Our teams are experts in drug and diagnostics discovery, technology transfer, and intellectual property. Our work is in translational science – bridging the gap between

academic research and clinical development, providing funding, research and expert knowledge, all with a clear and unwavering commitment to having a positive impact on patient lives. LifeArc is committed to spending £1.3 billion by 2030 in areas of high unmet medical need. LifeArc is a company limited by guarantee and a registered charity.

Find out more about our work on www.lifearc.org or follow us on [LinkedIn](#) or [Twitter](#).

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