

University-led COVID19 drug trial expands into home testing

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The trial of an inhaled drug that could prevent worsening of COVID-19 in those most at risk is to be expanded to dose patients in the home setting.

In March, the University of Southampton and drug development

company Synairgen began clinical tests of SNG001, a special, inhaled formulation of the naturally occurring antiviral protein interferon beta 1a on patients with COVID-19.

This new phase follows receipt of the necessary approvals to expand from the original 100 patients, to include enrolling an additional 120 patients in the [home environment](#).

The expanded trial includes patients who have had symptoms for less than 72 hours and are aged 50 or over with a high-risk comorbidity (such as cardiovascular disease, diabetes or a chronic lung condition), or aged 65 and over. Eligible patients are assessed via video call, and subsequently sent a swab by courier for self-swabbing. These swabs will be tested by Synairgen, and eligible patients with a positive sample will be sent a box containing all necessary equipment, aerosol delivery device, pulse oximeter, thermometer, other consumables and the study medication SNG001/placebo. The Southampton Clinical Trials Unit from the University of Southampton have joined forces with Synairgen to conduct the clinical trial, with additional support provided by the primary care delivery team at the NIHR Clinical Research Network Wessex (CRN Wessex).

Recruitment for the home setting of the trial will depend on the prevalence of the virus in the community and the degree to which the targeted 'at risk' patients become infected. The novel, virtual trial design, means it is readily scalable if necessary.

Professor Tom Wilkinson, Professor of Respiratory Medicine at the University of Southampton and Trial Chief Investigator, commented: "Expansion of the SG016 placebo controlled trial where we will be treating patients at the first sign of COVID-19 symptoms is something of a first and reflects the ingenuity and expertise of Synairgen and our researchers here at the University of Southampton. This novel approach

is designed to reduce infection risks for both patients and front-line workers. Critically, it also allows us to gather [clinical evidence](#) for SNG001 more quickly, a treatment we believe could play a crucial role in tackling the COVID-19 pandemic."

Richard Marsden, CEO of Synairgen, commented: "We are really pleased to be able to expand the SG016 trial to patients in the home environment which enables us to test the drug much earlier in the course of the illness. If successful, we would hope to protect the lungs and prevent the development of the severe lower respiratory tract illness which puts the healthcare system under such strain. We have also been pleased with the progress of the SG016 trial in the [hospital environment](#), having dosed 98 of 100 patients, and look forward to announcing top line data in July."

Interferon beta is a naturally occurring protein, which orchestrates the body's antiviral responses. There is evidence that deficiency in IFN-beta production by the lung could explain the enhanced susceptibility of these at-risk patient groups to developing severe lower respiratory tract (lung) disease during respiratory viral infections. Furthermore, viruses, including coronaviruses such as SARS-CoV-2 and MERS-CoV, have evolved mechanisms which suppress endogenous IFN-beta production, thereby helping the virus evade the innate immune system.

Professor Nick Francis, Professor of General Practice at the University of Southampton, commented: "This novel trial approach is essential for the ongoing health of those at higher risk because of increasing age or other risk factors. The approach could be rolled out across many areas of primary care involving the interaction with vulnerable patients, including the elderly, if it is successful. We are in desperate need of a treatment for COVID-19 that can be given to patients early in the course of the illness in order to prevent progression to severe symptoms."

The trial in COVID-19 patients is a double-blind, placebo-controlled trial. The treatment of patients in the hospital setting of the SG016 pilot trial is progressing well, with 98 [patients](#) out of 100 now dosed. Top line data is now expected in July. Patients in the hospital setting have typically had symptoms for a longer period of time, and the objective is to accelerate recovery and prevent progression of the disease from being able to breathe spontaneously (with or without oxygen) to requiring ventilation.

Data from the hospital initiated (late) patient and home initiated (early) patient populations will be analysed separately as soon as possible, and then together as one population at the end. Top line data from the trial in the hospital setting is expected in July 2020.

Synairgen is a respiratory drug discovery and development company founded by University of Southampton Professors Stephen Holgate, Donna Davies and Ratko Djukanovic.

More information can be found on the [study website](#).

Provided by University of Southampton

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