Academic and Clinical Central Office for Research and Development

Rapid Experimental Medicine for COVID-19 Induced Respiratory Failure

SUMMARY PARTICIPANT INFORMATION SHEET

DEFINE COVID-19

This information sheet is intended to provide summary information regarding the DEFINE COVID-19 trial. Please refer to the Main Information Sheet for a more detailed description of the trial drugs, procedures, risks and information on how your data will be stored and used.

You are being invited to consider whether you agree to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others or ask the research team any questions.

What is the purpose of the study?

We would like to look at new treatments for COVID-19 as it is a new and poorly understood infection. To do this we would like to give research participants experimental new treatments to see how their body responds compared to standard medical care.

How would you decide who gets the treatments?

We are trialling a number of new drugs – currently we have identified two potential treatments, but we may identify others in future. If you decide to take part in the trial, the research team will confirm which drugs would be suitable for you and you will then be randomly allocated (by a computer) to either one of the trial drugs **or** to continue with standard medical care only. If you are allocated to receive a trial drug, this will be given in addition to the usual care at your hospital. Trial treatments will be drugs that can be swallowed, inhaled or injected.

Taking part.

You do not have to take part in this research. We have approached you as you have been admitted to hospital and have tested positive for COVID-19. If you agree to take part we will ask you to sign a consent form and ask for some information about your medical history and current infection. If you are a person of childbearing potential, we will ask you to undergo a urine pregnancy test. Once allocated to a trial treatment or standard care, we will ask to take small daily samples of blood, saliva and nose/throat fluid and to check in on your progress for up to 16 days. We will then also conduct follow-up visits (either in person or by telephone) at 30, 60 and 90 days. We may also request a scan of your heart and lungs at the start and end of the study period and access to your medical records after the study to see how your health is.

Study treatment

The two new drugs we are currently testing are called Nafamostat and TD139.

If you are allocated to either of these treatments, the research team will describe how to take the treatment, any potential side effects and explain any additional procedures required. These will be explained in person and are also detailed in the main DEFINE COVID-19 Information Sheet provided. Throughout the trial, you will be monitored for any side effects and the trial treatment will be stopped if necessary.

Disadvantages

The study treatments may have some side effects, these are mostly mild and detailed in the main information sheet. Other disadvantages may include having to provide samples and undergo a scan. All sample taking will be carried out by experienced doctors and nurses and will be undertaken to minimise any discomfort. The other scans and tests are straightforward and will be thoroughly explained to you both before and during being carried out.

All samples taken and data will be kept confidential.

You can withdraw from the trial at any point and do not have to provide a reason.

Below is a summary of the consent and randomisation process alongside an outline of what is involved in each of the trial arms.