A New Clinical Research Study for Patients Hospitalised with COVID-19 is Now Enrolling

PATIENT INFORMATION GUIDE: THE SPRINTER STUDY
Clinical research studies are conducted to determine whether an investigational drug is safe and effective in treating a particular disease or condition. ‘Investigational’ means that the drug has not yet been approved for use in the wider population and is still being evaluated in studies such as the one described in this Information Guide.

Clinical research studies are performed according to strict governmental and ethical guidelines that help ensure that patients’ rights are protected while information about the investigational drug is collected.

**What is a clinical research study?**

**What is the SPRINTER Study?**

The SPRINTER Study is a Phase 3 clinical study; this means that researchers are testing the investigational drug in a large number of people with the target disease/condition. Before a drug can be evaluated in a Phase 3 clinical study, it will have been tested in a smaller group of people to assess both its safety and potential effectiveness in the patient population being investigated.

The aim of the SPRINTER Study is to assess the safety and effectiveness (how well something works) of an investigational drug called SNG001 in men and women hospitalised with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, also known as coronavirus disease 2019 (COVID-19).

COVID-19 has affected millions of people around the world. While the vast majority of people who get the virus will only have a mild infection, some people will need to go to hospital. Older people and those with certain co-morbidities appear to be at a higher risk for developing severe respiratory illness.
The SPRINTER Study is looking at an inhaled investigational study drug called SNG001. SNG001 is being used to replace a naturally occurring protein in your body (called interferon-β) that is normally involved in fighting infection. Researchers believe that in those who are at a higher risk of developing severe respiratory illness from COVID-19, levels of interferon-β are considerably reduced.

**Who can take part in the SPRINTER Study?**

Over 600 people are expected to take part in this study across the world; participants must:

- be aged ≥18 years
- have a confirmed positive test for COVID-19
- have been admitted to hospital and require low-flow oxygen
- not have previously been given a SARS-CoV-2 vaccination
- have provided their informed consent to participate.

There are other criteria that must be met to join the SPRINTER Study; the study team will have already discussed these with you and/or your family. Participation in the SPRINTER Study is entirely voluntary and you can withdraw from the study at any time. If you choose not to take part, you will not be disadvantaged in any way and you will continue to receive the medical care you would otherwise receive if not taking part in this clinical study.

**What is being investigated in the SPRINTER Study?**

The SPRINTER Study is looking at an inhaled investigational study drug called SNG001. SNG001 is being used to replace a naturally occurring protein in your body (called interferon-β) that is normally involved in fighting infection.

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**What will happen during the SPRINTER Study?**

In the SPRINTER Study, SNG001 will be compared with matching placebo. Placebo is something that looks similar to the investigational study drug but contains no active ingredients. You will be randomised to one of the following groups:

- **Group 1 - SNG001**
  - Over 300 patients
  - 2 doses
- **Group 2 - Placebo**
  - Over 300 patients
  - 2 doses

**Randomisation** is when something is assigned by chance, like drawing straws or pulling a number out of a hat, rather than any preference that you or the study doctor might have. Neither you nor the study team will know which study treatment group you have been assigned to either – the study is known as “blinded” when this happens.

SNG001 or placebo will be given by a nebuliser, which is a device used to administer certain drugs in the form of a mist, which is then inhaled into the lungs. These devices are commonly used for the treatment of respiratory diseases or disorders.

While in hospital, you will receive SNG001 or placebo once a day for 14 days under the supervision of the study team. At the end of the 14 days, your treatment will end and you will be monitored by the study team over the next 90 days.

You will also have a number of assessments during your participation in the study. Each day a member of the study team will check to see how you are feeling and assess the severity of your condition. You will be asked about symptoms you are experiencing (breathlessness, cough and sputum – the latter being a thick mucus that can get coughed up from your lungs when you are ill), your perceived quality of life and any possible side effects from the study drug. If you have been discharged from hospital before the end of the 14-day treatment period, these assessments will be done via telephone or video link at home; you will be asked to take any remaining study treatment at home. The study staff will supervise you doing this via telephone or video link.
**Study Overview**

The following figure provides an overview of the study timeline:

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BCSS = Breathlessness, Cough and Sputum Scale. Participants will be asked to record the severity of these three symptoms by selecting the applicable score for each symptom.

*You may be asked to give a small blood sample, for immunogenicity testing (to test your immune response), on Day 44; †includes assessment for long-COVID-19; ‡during the follow-up phase, home assessments will be conducted via telephone/video link.
What will happen if I am discharged from hospital before the end of my treatment?

Should you be discharged from hospital within 14 days of study start, you should continue your treatment at home for the remainder of your time in the study, i.e., if you are discharged on Day 3 of the study, you should take 22 doses home (please refer to the ‘Home administration information of study drug’ guide on the next page).

When you are discharged from hospital, you will be given the following items to enable you to continue taking your study medication at home:

• Your study medication – contained in syringes.
• The Aerogen® Solo nebuliser – this device is used to administer your study medication each day. Instructions on how to use the nebuliser will also be provided.
• Saline solution to clean the Aerogen nebuliser.
• A sharps container – each day, once you have loaded the medication into the nebuliser, the empty syringes should be placed in the yellow sharps container. The empty medication box can be placed in your normal household waste. Once all 14 doses have been completed, close the sharps container lid (it should click) so that it cannot be opened again. Keep in a secure place until it is possible to drop off at the hospital.
• An Emergency Contact Card – this contains numbers for the hospital study team for use in an emergency.
• A signed copy of the Patient Information Sheet and a consent form.
• A drug accountability log.
• Study questionnaires.

HOME ADMINISTRATION OF THE STUDY DRUG

You will have been trained on how to safely store the study drug, how to use the Aerogen® Solo nebuliser, and how to safely dispose of any equipment prior to your discharge from hospital.

For your reference, a summary of these steps is included below:

1. Store the syringes containing the study drug in your refrigerator when not in use. Ideally this should be away from any area of your fridge that tends to freeze, so storing it towards the front of your fridge is best.

2. Remove the syringes from the fridge at least 15 minutes before use and for no longer than two hours beforehand.

3. Open the plug on the Aerogen Solo.

4. Take the first syringes and remove the needle cap. Then, being careful not to spill any study medication, push the plunger down, placing all the study medication into the Aerogen Solo. Repeat step 4 with the second syringe.

5. Safely dispose of the syringes - use the sharps container you were given when you were discharged from hospital, taking care to avoid a needle stick injury. Never attempt to replace the cap back on the needle; dispose of the needle cap.

6. Close the plug on the Aerogen Solo.

7. Connect the Aerogen Ultra device to the power adaptor.

8. Sit comfortably in an upright position and place the clip on your nose.

9. Place the mouthpiece in your mouth and ensure there is a tight seal between the lips and the mouthpiece; start the nebuliser. Breathe normally through your mouth; do not breathe through your nose – ensure that the cloud of aerosol disappears from the chamber.  
   **Note:** each dose of study medication will take 2–6 minutes to be delivered.

10. Once completed, and if instructed to by the study staff, record that you have taken the study drug on the drug accountability log.

Repeat the above steps once a day at around the same time of day for the remainder of the study duration. There must be a gap of at least 8 hours between doses. You should write down the date and time you took the study drug in the drug accountability log you were provided with.

**Note:** To ensure optimal performance of the Aerogen Ultra, you can nebulise a few drops of normal saline, shake off the excess and allow to air dry.

The study team will call you via telephone or video call each day to assess your condition, help you with your medication/use of the nebuliser, record any symptoms, and answer any questions you may have.
If you need any further help or have any questions during your participation in the **SPRINTER Study**, you can contact the study team using the details below:

Contact name:  

Address:  

Telephone:  

Email:  

**SPRINTER**