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Phase III trial of inhaled SNG001 compared to placebo for the treatment of patients hospitalised due to moderate COVID-19

Submission date
18/01/2021

Recruitment status
No longer recruiting

Registration date
03/02/2021

Overall study status
Completed

Last Edited
31/03/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
SNG001 is an inhaled drug that contains interferon-β, an antiviral protein that occurs naturally in the body. Interferon-β has been given as an injection to thousands of patients for other diseases (such as multiple sclerosis); this study is about giving interferon-β by inhalation. By administering SNG001 directly into the lungs through a nebuliser (a device used to turn liquids into mists for breathing treatments), it is hoped that the interferon-β can boost the lungs' antiviral defences and help prevent deterioration in lung symptoms and help accelerate the recovery in patients already having breathing difficulties due to COVID-19. Recent research has suggested that interferon-β, if given by inhalation, might protect the cells in the lungs from viruses.
Early in 2020, Synairgen conducted a Phase II trial on SNG001 in patients hospitalised with COVID-19. The key findings from the placebo-controlled study in 101 patients were encouraging:
1. A two-fold increase in the likelihood of recovery, defined as 'no limitation of activities', during the treatment period.
2. SNG001 was very well tolerated in these hospitalised patients
SNG001 is an investigational drug which means it has not been approved as a marketed product (i.e. available to be prescribed and sold) by any regulatory authority. The aim of this study is to see if SNG001 helps COVID-19 participants recover more quickly from their illness and to find out if it is safe and effective in treating moderate COVID-19 compared to placebo (dummy drug).

Who can participate?
Adults ages 18 or over who are hospitalised with moderate COVID-19 and meet the study inclusion criteria and none of the exclusion criteria.

What does the study involve?
Patients will give informed consent to participate in the study. If eligible they will be randomly allocated to be treated with either SNG001 or placebo (dummy drug) and study assessments will be performed daily until day 35 and follow-up at various times until day 90. Patients will take the study medication daily for 14 days, this could be at hospital or at home if discharged from hospital.

What are the possible benefits and risks of participating?
It is hoped that SNG001 will help improve or treat COVID-19. However, participants may not get any direct benefit from taking part in this study. They will be given close attention from the study staff during the time they are involved in the study. They may get information about their health from physical examinations and medical tests done in this study. If the results of this study are favourable and, along with extra studies, lead to approval by regulatory authorities for use in humans, there may be benefits for patients in the future.

Where is the study run from?
Synairgen Research Ltd (UK)

When is the study starting and how long is it expected to run for?
August 2020 to February 2022

Who is funding the study?
Synairgen Research Ltd (UK)

Who is the main contact?
Sophie Hemmings
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Contact information

Type(s)
Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04732949

Clinical Trials Information System (CTIS)
2020-004743-83

Integrated Research Application System (IRAS)
290965

Central Portfolio Management System (CPMS)
47416

Protocol serial number
SG018, , , UPH

Study information

Scientific Title
A randomised, double-blind, placebo-controlled, phase III trial to determine the efficacy and safety of inhaled SNG001 for the treatment of patients hospitalised due to moderate COVID-19

Acronym
SPRINTER

Study objectives
The aim of this Phase III study is to confirm that SNG001 can accelerate the recovery of hospitalised patients receiving oxygen with confirmed SARS-CoV-2. Safety and other efficacy endpoints will also be assessed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/11/2020, London - Riverside Research Ethics Committee (Level 3 Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8340; riverside.rec@hra.nhs.uk), REC ref: 20/HRA/5234

Primary study design
Interventional

Study design
Multi-centre interventional double-blind placebo-controlled randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
SNG001 or placebo, randomised via IWRS, 1:1 ratio.
Dose: two syringes of either SNG001 (per syringe; 0.65 ml of drug product solution at a concentration of 12 MIU/ml) or placebo (per syringe; 0.65 ml of excipients only) taken once daily for 14 days.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
SNG001 (inhaled interferon-β)

Primary outcome(s)
1. Time to hospital discharge, considered when Ordinal Scale for Clinical Improvement (OSCI) score is 2 (limitation of activities) or below with no rebound at subsequent assessments, from day 1 until day 28
2. Time to recovery, defined as an OSCI score of 1 (no limitation of activities) or below with no rebound at subsequent assessments, from day 1 until day 28

Key secondary outcome(s)
1. Progression to severe disease or death, defined by the OSCI score of 5 (non-invasive ventilation or high-flow oxygen) or above within 35 days of first dose
2. Progression to intubation or death, defined by the OSCI score of 6 (intubation and mechanical ventilation) or above within 35 days of first dose
3. Death, defined by the OSCI score of 8 (death) within 35 days of first dose

Completion date
10/02/2022

Eligibility

Key inclusion criteria
1. Male or female, ≥18 years of age at the time of consent
2. Admitted to hospital due to the severity of their COVID-19
3. Positive virus test for SARS-CoV-2 using a validated molecular assay or antigen assay. Patients who had positive virus test for SARS-CoV-2 prior to hospitalisation will be randomised no later than 48 hours after hospital admission. If the virus test was performed more than 96 hours prior to hospitalisation, the test will have to be repeated in the hospital prior to randomisation. Only

patients whose repeated virus test is positive will be randomised, no later than 48 hours after confirmation of SARS-CoV-2 infection. Patients who had positive virus test for SARS-CoV-2 after hospitalisation will be randomised no later than 48 hours after confirmation of SARS-CoV-2 infection
4. Require oxygen therapy via nasal prongs or mask (OSCI score of 4)
5. Provided informed consent
6. Female patients must be ≥1 year post-menopausal, surgically sterile, or using a highly effective method of contraception

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
623

Key exclusion criteria
1. Evidence of ongoing SARS-CoV-2 infection for more than 3 weeks, confirmed by a validated molecular assay or validated antigen assay
2. Non-invasive ventilation or high-flow oxygen (OSCI score of 5)
3. Mechanical ventilation (continuous or intermittent CPAP or intubation) or admission to intensive care (OSCI score of ≥6)
4. Previous SARS-CoV-2 infection confirmed by a validated molecular assay or validated antigen assay
5. Any condition, including findings in the patients' medical history or in the pre-randomisation study assessments that in the opinion of the Investigator, constitute a risk or a contraindication for the participation of the patient into the study or that could interfere with the study objectives, conduct or evaluation
6. Participation in previous clinical trials of SNG001
7. Current or previous participation in another clinical trial where the patient has received a dose of an Investigational Medicinal Product (IMP) containing small molecules within 30 days or 5 half-lives (whichever is longer) prior to entry into this study or containing biologicals within 3 months prior to entry into this study
8. Inability to use a nebuliser with a mouthpiece
9. Inability to comply with the requirements for storage conditions of study medication in the home setting
10. History of hypersensitivity to natural or recombinant IFN-β or to any of the excipients in the drug preparation
11. Females who are breastfeeding, lactating, pregnant or intending to become pregnant
12. Previous SARS-CoV-2 vaccination

Date of first enrolment
12/01/2021

Date of final enrolment
11/11/2021

Locations

Countries of recruitment
United Kingdom

England

Argentina

Belgium

Brazil

Colombia

France

Germany

India

Israel

Italy

Mexico

Netherlands

Portugal

Romania

Serbia

Spain

United States of America

Study participating centre
Southampton General Hospital
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Study participating centre
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Study participating centre
Queen Elizabeth Hospital Birmingham
Respiratory - University Hospitals Birmingham NHS Foundation Trust
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B15 2GW

Sponsor information

Organisation
Synairgen Research Ltd

Funder(s)

Funder type
Industry

Funder Name
Synairgen Research Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/03/2023	31/03/2023	Yes	No
HRA research summary			28/06/2023	No	No