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A Phase II study to understand the safety and effects of inhaled SNG001, the study medication, in patients who are mechanically ventilated due to a respiratory viral infection in the lungs

Submission date
09/11/2024

Recruitment status
Recruiting

Registration date
29/01/2025

Overall study status
Ongoing

Last Edited
12/02/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to assess if the medicine (SNG001) could potentially be a treatment for patients who have severe viral lung infections ('pneumonia') such as those caused by flu or COVID-19. SNG001 contains interferon-β, a protein that occurs naturally in humans, which helps the body's immune system fight off viruses. Clinical trials have shown that SNG001 has anti-viral activity and potential beneficial effects on clinical outcomes in patients with viral infections in the lung. In critically ill patients who require mechanical ventilation due to severe viral pneumonia, SNG001 could help clear the infection and thereby improve outcomes and recovery. SNG001 is delivered by inhalation using a nebuliser to target the virus in the lungs. SNG001 has been extensively evaluated in other patient groups including those with COVID-19, COPD and asthma.

Who can participate?
Patients who require mechanical ventilation due to a virus infection in the lung

What does the study involve?
This study has two parts. Part 1 will assess the safety of SNG001. A small group of participants will receive a low dose. Based on recommendations from an independent safety committee, a second group may receive a higher dose. The dose for Part 2 will be determined by the results from Part 1. Part 2 will evaluate how effective SNG001 is compared to placebo in up to 450 Participants who will be randomly allocated to receive either SNG001 or placebo. They will be dosed for 14 days or until hospital discharge whichever happens first. During the study participants will still receive standard of care including other treatments for viral pneumonia

What are the possible benefits and risks of participating?
The potential health benefit from participating in this study is that SNG001 may help patients

recover from their lung infection, shorten their symptoms and/or shorten the length of time they will need to be on a ventilator. In addition, the results of this study will be used for future product development decisions to improve SNG001. Information learned from the study may help other people in the future.
SNG001 has been investigated in seven completed clinical studies, across various populations including asthmatics, COPD and COVID-19 patients. Of the 758 patients treated with SNG001, 342 patients with COVID-19 required hospitalisation and oxygen supplementation due to the severity of their disease. Treatment with SNG001 across the different studies was generally well tolerated, with no specific safety signals being observed, whether related to local tolerance or systemic effects. SNG001 has not been administered to patients with severe viral lung infections undergoing IMV hence the specific focus of Part 1 of the study on safety. A review of the safety data and potential risks supports the design of the proposed clinical trial (SG021) of SNG001. To minimize any potential risks Part 1 of the study will initially assess safety in patients receiving a lower dose of SNG001. The independent data review committee will provide ongoing oversight of safety throughout both parts of the study.

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

When is the study starting and how long is it expected to run for?
November 2024 to March 2027

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

Who is the main contact?
Sophie Hemmings, submissions@synairgen.com

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1010122

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SG021, CPMS 62305

Study information

Scientific Title
A Phase II, two-part study to assess the safety, antiviral biomarker responses, and efficacy of inhaled SNG001 for the treatment of patients with a confirmed respiratory virus infection undergoing invasive mechanical ventilation

Study objectives
The primary objective of Part 1 will be to evaluate the safety of SNG001 administration to participants with a confirmed respiratory virus infection undergoing IMV.

The primary objective of Part 2 will be to evaluate the efficacy of SNG001, versus placebo, in participants with a confirmed respiratory virus infection undergoing IMV.

Secondary objectives of part 2:
1. To evaluate the safety of SNG001 administration to participants with a confirmed respiratory virus infection undergoing IMV.
2. To evaluate antiviral and biomarker responses after administration of SNG001.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted, ref: 24/SC/0385

Study design
Double-blind randomized placebo-controlled parallel-group trial (Part 1 of the study is open-label, uncontrolled, to assess the safety of SNG001)

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Respiratory viral infections

Interventions
Part 1 (Open-label; non-comparative):
Participants who meet study entry criteria will receive the following intervention:

Experimental Arm:
Cohort 1, SNG001 (0.65 ml of nebuliser solution containing 12 MIU/ml of IFNβ-1a) given by inhalation using a nebuliser, once a day for a maximum of 14 days or until hospital discharge whichever occurs earlier, in addition to Standard of Care (SOC).
Cohort 2 (Optional), SNG001 (at a dose recommended by the IDMC) given by inhalation using a nebuliser, once a day for a maximum of 14 days or until hospital discharge whichever occurs earlier, in addition to SOC.

Part 2 (Randomized; double-blind; placebo-controlled):
Participants who meet study entry criteria will be randomised (using an online tool) to receive either of the following interventions:

Experimental Arm:
SNG001 (at a dose recommended by the IDMC, (based on results of Part 1) of nebuliser solution containing 12 MIU/ml of IFNβ-1a) given by inhalation using a nebuliser, once a day for a maximum of 14 days or until hospital discharge whichever occurs earlier, in addition to SOC.

Placebo Comparator Arm:
SNG001 placebo to match experimental arm (based on results of Part 1) of nebuliser solution identical to the experimental arm but without IFNβ-1a) given by inhalation using a nebuliser, once a day for a maximum of 14 days or until hospital discharge whichever occurs earlier, in addition to SOC.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Interferon beta-1a (IFN-β1a)

Primary outcome(s)
Part 1: The occurrence and severity of adverse events (AEs) and serious adverse events (SAEs), including prespecified respiratory and cardiovascular deteriorations, assessed by site staff using recognised assessment tools and/or patients' clinical condition, up to 28 days from

randomisation
Part 2: All-cause mortality within 28 days from randomisation measured using the proportion of patients who died between randomisation and day 28 in each study arm

Key secondary outcome(s))
Part 1: None

Part 2:
1. The occurrence and severity of AEs and SAEs, including pre-specified respiratory and cardiovascular deteriorations, assessed by site staff using recognised assessment tools and/or patients' clinical condition, up to Day 42
2. Organ failure assessed using the modified Sequential Organ Failure Assessment (mSOFA) score (5-point scores for the different organ systems) daily during ICU stay up to day 15
3. Time to extubation, defined as the date free from all tubes (endotracheal tube and tracheostomy tube), which was sustained for a minimum of 48 hours, up to 28 days from randomisation
4. Ventilator-free days over 28 days from randomisation measured using the mean number of days between randomisation and day 28 in each study arm when patients were not receiving mechanical ventilation
5. Duration of ICU stay up to 28 days from randomisation measured using the mean number of days between randomisation and day 28 in each study arm when patients were staying in the ICU
6. Duration of hospital stay up to 28 days from randomisation measured using the mean number of days between randomisation and day 28 in each study arm when patients were staying in the hospital
7. Clinical improvement assessed using the Ordinal Scale for Clinical Improvement (OSCI) score (8-point scale) from baseline to 7, 10, 14 and 28 days post-randomisation
8. Time to first negative virus test in tracheal aspirates assessed daily up to Day 7 by reverse transcription polymerase chain reaction (RT-PCR) test
9. Levels of IFNβ-dependent biomarkers in tracheal aspirates measured using PCR daily up to Day 7

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Part 1:
1. Informed consent or legal representative's consent obtained
2. Patients ≥50 years of age at the time of consent
3. Patient admitted to the ICU and requiring IMV due to a respiratory virus infection*
4. Presence of Influenza A (Flu A), Influenza B (Flu B), respiratory syncytial virus (RSV), rhinovirus (RV), adenovirus, parainfluenza, human metapneumovirus (HMPV), or coronaviruses (including SARS COV 2 and seasonal coronaviruses) in an LRT sample, confirmed by a positive virus test using a Sponsor approved rapid POC test (e.g., reverse transcription polymerase chain reaction [RT-PCR]), with a reported cycle threshold (Ct) value that meets the criteria as specified for each virus in Appendix A**
5. Time from intubation to administration of first dose of study medication ≤48 hours
6. Women of childbearing potential must have a negative pregnancy test. For this study, women of childbearing potential are defined as women <55 years old

Part 2:
1.1. Patients ≥18 and <50 years of age at the time of consent, with an immunocompromising condition, including:
1.1.1. Haematological malignancy;
1.1.2. Bone marrow transplantation; or
1.1.3. Immunosuppressive therapy, including cancer chemotherapy, immune-cell depleting therapy, immunosuppressive therapy for autoimmune disorders, medications for prevention of organ transplantation rejection, or the administration of corticosteroids >20 mg of prednisone or equivalent per day administered continuously for >14 days prior to randomisation
or
1.2. Patients ≥50 years of age at the time of consent, with or without an immunocompromising condition
2. Patient admitted to the ICU and requiring IMV due to a respiratory virus infection*
3. Presence of Flu A, Flu B, RSV, RV, adenovirus, parainfluenza, HMPV, or coronaviruses (including SARS-COV-2 and seasonal coronaviruses) in an LRT sample, confirmed by a positive virus test using a Sponsor approved rapid POC test (e.g., RT PCR), with a reported Ct value that meets the criteria as specified for each virus in Appendix A**
4. Time from intubation to administration of first dose of study medication ≤48 hours
5. Informed consent or legal representative's consent obtained
6. Women of childbearing potential must have a negative pregnancy test. For this study, women of childbearing potential are defined as women <55 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Part 1:
1. Expected termination of IMV within 24 hours from the time of randomisation
2. Life expectancy <24 hours
3. Liver failure (Child-Pugh C)
4. Severe congestive heart failure (New York Heart Association [NYHA] IV)
5. Receipt of lung transplant
6. Known or suspected active tuberculosis, or infection with other mycobacteria
7. Known or suspected systemic fungal infection
8. Anticipated transfer to another hospital
9. Current need for long-term mechanical ventilation
10. Use of inhaled sedation
11. Requirement for airway pressure release ventilation mode
12. History of hypersensitivity to natural or recombinant IFNβ or to any of the excipients in the

drug preparation
13. Any condition, including findings in the patient's medical history or in the pre-randomisation study assessments that in the opinion of the Investigator, constitute a risk or a contraindication for participation in the study or that could interfere with the study objectives, conduct, or evaluation.
14. Participation in previous clinical studies of SNG001
15. Current or previous participation in another clinical study where the participant 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
16. Known or suspected pregnancy
17. Females who are breastfeeding or lactating
18. Immunocompromising condition, including:
18.1. Established acquired immune deficiency syndrome (AIDS) defined as a cluster of differentiation 4 (CD4) count <200 cells/microL, and/or the presence of any AIDS-defining condition;
18.2. Haematological malignancy;
18.3. Bone marrow transplantation; or
18.4. Immunosuppressive therapy including cancer chemotherapy, immune-cell depleting therapy, immunosuppressive therapy for autoimmune disorders, medications for prevention of organ transplantation rejection, or the administration of corticosteroids >20 mg of prednisone or equivalent per day administered continuously for >14 days prior to randomisation
19. Severe chronic lung disease requiring home oxygen therapy, including chronic obstructive pulmonary disease, asthma, cystic fibrosis, or pulmonary fibrosis

Part 2:
1. Expected termination of IMV within 24 hours from the time of randomisation
2. Life expectancy <24 hours
3. Liver failure (Child-Pugh C)
4. Severe congestive heart failure (NYHA IV)
5. Receipt of lung transplant
6. Known or suspected active tuberculosis, or infection with other mycobacteria
7. Known or suspected systemic fungal infection
8. Established AIDS, defined as a CD4 count <200 cells/microL, and/or the presence of any AIDS-defining condition
9. Anticipated transfer to another hospital
10. Current need for long-term mechanical ventilation
11. Use of inhaled sedation
12. History of hypersensitivity to natural or recombinant IFNβ or to any of the excipients in the drug preparation
13. Any condition, including findings in the patient's medical history or in the pre-randomisation study assessments that in the opinion of the Investigator, constitute a risk or a contraindication for participation in the study or that could interfere with the study objectives, conduct, or evaluation
14. Participation in previous clinical studies of SNG001
15. Current or previous participation in another clinical study where the participant has received a dose of an 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
16. Known or suspected pregnancy
17. Females who are breastfeeding or lactating

Date of first enrolment
31/03/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Synairgen (United Kingdom)

ROR
https://ror.org/04h6ep125

Funder(s)

Funder type
Industry

Funder Name
Synairgen Research Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes