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# SPL7013 Nasal Spray safety and performance in patients with COVID-19

**Submission date**
28/11/2022

**Recruitment status**
No longer recruiting

**Registration date**
01/12/2022

**Overall study status**
Completed

**Last Edited**
12/09/2024

**Condition category**
Infections and Infestations

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

## Plain English summary of protocol

Background and study aims
SPL7013 Nasal Spray is intended to trap and block cold and respiratory viruses in the nasal cavity before an infection develops fully. SARS-CoV-2 (coronavirus) is a respiratory virus that can lead to the respiratory illness, COVID-19. Symptoms of COVID-19 include, but are not limited to, fever (high body temperature), coughing, sore throat, fatigue (tiredness), and shortness of breath, and the disease has been associated with hospital intensive care admissions and a significant death rate. Viruses, like SARS-CoV-2, act by attaching themselves to receptors on human cells. Attachment to these receptors allows the virus to enter, or infect, these cells and cause replication of the virus that is then released from the cells and can infect other cells in the body. The receptors that SARS-CoV-2 binds to are found in high numbers on cells that line the nasal cavity, and these cells are a key target for initial infection. Therefore, it has been proposed that a product that can stop respiratory viruses such as SARS-CoV-2 from accessing and attaching to the cells in the nasal cavity could help prevent or treat respiratory disease by reducing exposure to viruses.
SPL7013 Nasal Spray works by forming a barrier that contains a molecule called SPL7013, which can trap viruses before they access and attach to cells. The nasal spray containing SPL7013 is a medical device registered and marketed in several European countries and in the UK under the brand name, Viraleze™.
SPL7013 Nasal Spray has been applied to the nasal cavity of healthy volunteers under controlled conditions in a clinical trial and was demonstrated to be well tolerated when used four times a day for 14 days. The aim of this study is to add to the current data by testing the performance and safety of SPL7013 Nasal Spray in COVID-19 patients. The aim is to determine the performance of SPL7013 Nasal Spray at reducing the amount of SARS-CoV-2 virus in the nasal cavity of people with COVID-19, and to assess if there are any adverse effects.

Who can participate?
Adults over the age of 16 years with a recent diagnosis of COVID-19. This investigation is not open to women who are pregnant, planning to become pregnant or breastfeeding.

What does the study involve?
Participants with a positive PCR test for COVID-19 will be randomly allocated to the SPL7013 Nasal Spray group or the control group. Participants in the control group will receive the placebo

nasal spray, which is a spray that does not contain SPL7013. Participants will use the nasal spray four times daily for 7 days. During these 7 days, participants will take swabs daily to allow for measuring the amount of virus in the nasal cavity, and complete an online questionnaire about symptoms and other medical information. Participants will attend a final visit to the site on Day 8 to return their nasal spray and undergo a final examination by the investigator.

What are the possible benefits and risks of participating?
For those allocated to SPL7013 Nasal Spray, use of the spray may reduce the amount of virus in the nasal cavity, which may help to ease or reduce symptoms and help with recovery. No benefits are anticipated for those randomised to placebo nasal spray.
In a previous study of SPL7013 Nasal Spray in healthy volunteers, a small number of participants reported headache, nasal discomfort, nasal congestion, runny nose or nosebleed. These events were observed at similar rates in both SPL7013 Nasal Spray and placebo-treated participants. There may be additional adverse effects in humans that are not yet known. As with any other treatment, there is the potential risk of anaphylaxis - a severe allergic reaction that can cause itchy rash, throat swelling, and a drop in blood pressure, although this type of reaction has not previously been observed with products containing SPL7013.

Where is the study run from?
St Peter's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2022 to October 2023

Who is funding the study?
Starpharma Pty Ltd (Australia)

Who is the main contact?
1. Dr Jeremy Paull
jeremy.paull@starpharma.com
2. Dr Stephen Winchester
s.winchester@nhs.net

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Stephen Winchester

### Contact details
St Peter's Hospital
Guildford Rd
Chertsey
United Kingdom
KT16 0PZ
+44 (0)1932723712
s.winchester@nhs.net

### Type(s)

Public

**Contact name**
Dr Jeremy Paull

**ORCID ID**
https://orcid.org/0000-0002-9981-421X

**Contact details**
Starpharma Pty Ltd
4-6 Southampton Crescent
Abbotsford
Australia
3067
+61 (0)385322736
jeremy.paull@starpharma.com

**Type(s)**
Scientific

**Contact name**
Dr Jeremy Paull

**Contact details**
Starpharma Pty Ltd
4-6 Southampton Crescent
Abbotsford
Australia
3067
+61 (0)385322736
jeremy.paull@starpharma.com

# Additional identifiers

**Integrated Research Application System (IRAS)**
320408

**Central Portfolio Management System (CPMS)**
54894

**Protocol serial number**
SPL7013-022

# Study information

**Scientific Title**
A randomized, double-blind, placebo-controlled investigation to evaluate the performance and safety of SPL7013 Nasal Spray in non-hospitalised patients with COVID-19

**Study objectives**

SPL7013 Nasal Spray is superior to placebo at reducing SARS-CoV-2 viral burden in non-hospitalised patients with COVID-19.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 29/11/2022, East Midlands – Leicester Central Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8066; leicestercentral.rec@hra.nhs.uk), ref: 22/PR/1378

## Primary study design
Interventional

## Study design
Double-blind multicentre interventional randomized placebo-controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Reduced viral burden and prevention of disease progression in non-hospitalised patients with COVID-19 (SARS-CoV-2 infection)

## Interventions
Randomisation will be performed using a site-specific, computer-generated randomisation list that is based upon a permutation block procedure. The randomisation list will link the treatment group with the unique randomisation number that is allocated to each eligible participant at the time of enrolment and registration in the electronic data capture system.

Patients will be randomised 1:1 to:
1. SPL7013 Nasal Spray (containing 1% SPL7013 [astodrimer sodium])
2. Placebo - Saline Nasal Spray

Patients will self-administer one spray (~0.1 ml) per nostril four times daily for 7 days.

## Intervention Type
Device

## Phase
Phase IV

## Drug/device/biological/vaccine name(s)
SPL7013 (astodrimer sodium) Nasal Spray

## Primary outcome(s)
Area under the curve (AUC) of nasal swab SARS-CoV-2 viral load measured using reverse transcription quantitative real-time polymerase chain reaction (RT-qPCR) through Day 7

## Key secondary outcome(s)

1. Peak nasal swab SARS-CoV-2 viral load measured using RT-qPCR on Days 1-8
2. Mean change in nasal swab SARS-CoV-2 viral titre, measured using RT-qPCR, at each viral load determination (Day 2-8) from baseline viral load at screening (i.e., prior to randomisation)
3. Time to negative SARS-CoV-2 RT-qPCR (to Day 8)
4. Number of days between the start and complete resolution of acute COVID-19-related symptoms measured using the FLU-PRO Plus questionnaire to Day 8
5. Disease progression to a score of 4 or more measured on the World Health Organization Clinical Progression Scale (WHO CPS) by Day 7
6. Frequency and severity of adverse events (AEs) as measured by participant report and investigator detection (Day 1-8)

### Completion date
31/10/2023

## Eligibility

### Key inclusion criteria
1. Females and males aged 16 years and older
2. Positive PCR test for COVID-19 within 2 days (if possible 24 hours) of enrolment
3. Score of 1 to 3 on the WHO Clinical Progression Scale (CPS)
4. Able to understand and willing to comply with the investigation plan procedures and restrictions

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
16 Years

### Sex
All

### Total final enrolment
231

### Key exclusion criteria
1. Allergy to any ingredient in the device formulation (SPL7013, parabens, Carbopol 974P, glycerine, propylene glycol, or EDTA)
2. Treated or about to be treated with medications administered by inhalation (with exception of asthma-related treatment) or via the nasal route
3. Pregnant, planning to become pregnant, or breastfeeding, or within 3 months of last pregnancy outcome
4. In the opinion of the investigator, should not participate in the investigation

**Date of first enrolment**
05/12/2022

**Date of final enrolment**
22/09/2023

# Locations

**Countries of recruitment**
United Kingdom

England

Pakistan

**Study participating centre**
**St Peter's Hospital**
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

# Sponsor information

**Organisation**
Starpharma (Australia)

**ROR**
https://ror.org/018xv9w84

# Funder(s)

**Funder type**
Industry

**Funder Name**
Starpharma Pty Ltd

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the study will be available upon request from the Sponsor subject to an approved analysis plan and execution of a data-sharing agreement.

Name and email address of who should be contacted for access to the datasets: Jeremy Paull (jeremy.paull@starpharma.com)
Type of data to be shared: anonymized data only; other information to be further determined and added to the record at a later stage
Dates of availability: to be determined and added to the record at a later stage
Whether consent from participants was required and obtained: specific consent to make data available on request to interested parties is not required as data are anonymized
Comments on data anonymization: all data will be anonymized; no personal information is to be made available
Any ethical or legal restrictions: none at this time
Any additional comments: none at this time

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 06/09/2024 | 12/09/2024 | Yes | No |