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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
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
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2. Dr Stephen Winchester
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Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320408

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPL7013-022, IRAS 320408, CPMS 54894

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 hypothesis
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format; please use contact details to request a participant information sheet

Condition
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 measure
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

Secondary outcome measures
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)

Overall study start date
01/09/2022

Overall study end date
31/10/2023

Eligibility

Participant 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

Age group
Adult

Lower age limit
16 Years

Sex

Both

Target number of participants
160

Total final enrolment
231

Participant 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

Recruitment start date
05/12/2022

Recruitment end date
22/09/2023

Locations

Countries of recruitment
England

Pakistan

United Kingdom

Study participating centre
St Peter's Hospital
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Sponsor information

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Starpharma (Australia)

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Sponsor type
Industry

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ROR
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Funder(s)

Funder type
Industry

Funder Name
Starpharma Pty Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2024

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