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Effects of ethyl lauroyl arginine nasal spray on COVID-19

Submission date
23/04/2022

Recruitment status
No longer recruiting

Registration date
26/04/2022

Overall study status
Completed

Last Edited
26/08/2022

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
This study will test a formulation, Ethyl Lauroyl Arginate Hydrochloride [LAEH], 0.1% concentration (referred to as the "study product") formulation in subjects having mild Coronavirus-19 (COVID-19) disease.
The purpose of this study is to compare the effect of study product and placebo (does not have any active ingredient) administered as a nasal spray for reducing viral load levels in nasal areas of mild COVID-19 positive subjects.

Who can participate?
Adults over 18 years, with Covid-19 infection confirmed by RT-PCR test

What does the study involve?
Participants will be randomly allocated to receive Covixyl-V LAEH nasal spray for 6 days or a placebo spray for 6 days.

What are the possible benefits and risks of participating?
The possible benefits to the subjects in the study are reduction in viral load in the nasal passages along with stopping viral transmission/spread to others. This may or may not decrease your symptoms or COVID-19 infection.
If you agree to take part in this study, there may not be a direct medical benefit to you. We hope the information learned from this study will benefit other patients diagnosed with COVID-19 in the future.
There are minimal physical risks and discomfort to you in this study. No blood tests or medical interventions will be performed as part of this research.
The study staff will collect swabs from nasal passages which at times cause some discomfort to you. You may experience discomfort, eyes watering, sneezing, or bleeding.

Where is the study run from?
Miami Lakes Medical Center (USA)

When is the study starting and how long is it expected to run for?
June 2021 to October 2021

Who is funding the study?
Salvacion LLC (USA)

Who is the main contact?
Dr Abdul Gaffar, abdulgaffar535@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Protocol serial number
00054373

Study information

Scientific Title
A randomized, double-blind, multicenter study to evaluate the efficacy and safety of ethyl lauroyl arginine hydrochloride (ELAH) formulation administered as a nasal spray to reduce viral load in the nasal area in subjects with coronavirus disease 2019 (COVID-19)

Acronym
ELAH

Study objectives
To evaluate and compare the safety and efficacy of LAEH nasal spray (0.1% concentration) against a matching placebo nasal spray, administered to reduce viral load from the nasal area of subjects with Coronavirus Disease 2019 (COVID-19).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/06/2021, Adverra IRB (6100 Merriweather, suite 600, Columbia MD 20-21044, USA; +1 877-922-4724; no email provided), ref: 00054373

Primary study design
Interventional

Study design
Interventional double-blind randomized placebo-controlled trial

Study type(s)
Prevention

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

Interventions
Subjects were enrolled after obtaining written informed consent and were screened for eligibility for the study based on inclusion and exclusion criteria. For confirmation of COVID-19, subjects underwent Reverse transcription polymerase chain reaction (RT-PCR) test. Only those subjects who had laboratory-confirmed diagnosis of COVID-19 at the time of screening (Day -3 to 0) using RT-PCR method and who met all eligibility criteria were enrolled. Along with viral load values from RT-PCR test, cycle threshold (CT) value was also included in the laboratory reports.
Subjects with COVID-19 were randomized into this study with Covixyl-V LAEH nasal spray and placebo nasal spray. Subjects were randomized in a 1:1 proportion to receive either LAEH formulation or matching placebo twice daily.
Subjects were instructed to use the assigned treatment as nasal spray (2 to 3 puffs in each nostril at a time) twice a day from Day 1 to Day 5 and only once in the morning on Day 6.
Subjects were instructed to refrain from eating, drinking, or using any nasal gavage at least 30 minutes prior to use of nasal spray. Subjects were also informed that the daily second treatment should be taken approximately 6 hours after the first treatment. The site personnel explained the effective use of the nasal spray in a step-by-step manner and documented the same training in the source documents. The subjects were instructed to record his/her initials and date and time he/she administered the assigned treatment on a daily basis in the subject diary. On Day 6 /end of study (EOS), all the subjects took the first treatment (11th dose) at home around 8:00 am and then visited their respective site as instructed. Then the site performed the viral load enumeration using RT PCR test (including CT value) within 3 and 6 hours post last dose (at end of 11th treatment).
Group A assessed subjects with COVID-19 who received Covixyl-V LAEH nasal spray for 6 days.
Group B assessed subjects with COVID-19 who received placebo nasal spray for 6 days.
The site called each subject daily and collected information on Adverse Events (AEs) (if any), concomitant medications, and treatment compliance and completion of subject diary. Adverse Events (AEs) were collected after signing of informed consent through the end of the study.
The frequency of assessment was at screening/baseline and on Day 6.
RT-PCR testing was performed for confirmation of positive COVID-19 test, and enumerating viral load (including CT value). Vital signs such as blood pressure (BP), heart rate (HR), respiratory rate (RR), Oxygen saturation (SpO2), body temperature were noted and nasal and physical examination was performed.
Safety and tolerability of Covixyl-V LAEH nasal spray were assessed by evaluating AEs, serious adverse events (SAEs), vital signs, treatment discontinuation due to AEs, and nasal and physical examinations.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Covixyl-V (ethyl lauroyl arginine hydrochloride [ELAH] nasal spray)

Primary outcome(s)
1. Viral load measured using RT-PCR test post treatment (day 6)
2. Number of Covid-19 free subjects measured using RT-PCR test post treatment (day 6)

Key secondary outcome(s)
Safety and tolerability of Covixyl-V LAEH nasal spray were assessed by evaluating AEs, serious adverse events (SAEs), vital signs, treatment discontinuation due to AEs, and nasal and physical examinations using patient records at the end of the study

Completion date
04/10/2021

Eligibility

Key inclusion criteria
1. Signed informed consent
2. Confirmed for Covid-19 infection by RT-PCR tests

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Allergy to ELAH
2. Females who were breast feeding or lactating
3. History of severe respiratory infections
4. Have received period Covid treatment
5. Participated in any interventional drug trial in previous 30 days

Date of first enrolment
02/08/2021

Date of final enrolment

04/10/2021

Locations

Countries of recruitment
United States of America

Study participating centre
Miami Lakes Medical Center
2300 W 84 Suite, 84
Hialiah
United States of America
33016

Sponsor information

Organisation
Salvacion LLC

Funder(s)

Funder type
Industry

Funder Name
Salvacion LLC

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
Other unpublished results	version 0.1	19/11/2021	26/08/2022	No	No
Participant information sheet		15/06/2021	26/04/2022	No	Yes

Preprint results	10/03/2022	09/08/2022	No	No