

Inhalation of Sodium Pyruvate to Reduce the Symptoms and Severity of Respiratory Diseases Including COVID-19, Long COVID, and Pulmonary Fibrosis

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Overview

To combat the continuing COVID-19 pandemic, and to treat the symptoms in long COVID (hypoxemia (low SaO₂), fatigue, coughing/sneezing, trouble breathing, body aches, headaches and pulmonary fibrosis), N115 (sodium pyruvate) was chosen because of its safety and efficacy profile after treating 3.5 million patients in over 200 hospitals globally with no adverse events reported.

In 19 Phase I, II, III FDA human clinical trials, against a saline placebo, only N115 reduced inflammation and oxygen radicals and inflammatory cytokines including IL-6, a cause of the cytokine storm in patients with an active COVID-19 infection.

In prior clinical trials, N115, not the saline placebo, reduced congestion and coughing while increasing lung functions, increasing the synthesis of NO, and increasing SaO₂ levels in thousands of patients including patients with varying lung diseases like COPD, Pulmonary Fibrosis (PF), Cystic Fibrosis, Allergic Rhinitis, Sinusitis and Influenza infected patients.

Numerous studies have shown oxidative stress to be associated with Pulmonary Fibrosis, including Long COVID patients with Pulmonary Fibrosis, and that antioxidants are effective in attenuating fibroproliferative responses in the lungs of animals and humans.

Sodium Pyruvate is a natural antioxidant of the human body that inhibits Fibrosis and we received Orphan Drug Designations for the treatment of Cystic Fibrosis and Pulmonary Fibrosis. The objective of the clinical trials reported here was to study the safety and efficacy of N115 and changes in lung function and COVID symptoms in acute virally infected COVID-19 patients, patients with chronic symptoms after COVID-19.

Background:

To combat the continuing COVID-19 pandemic, and to treat the symptoms in Long COVID patients with a safe, effective, and inexpensive treatments are needed. Patients recovering from severe COVID-19 are at serious risk of developing Pulmonary Fibrosis.

Conversely, patients with Pulmonary Fibrosis have an increased risk and susceptibility to COVID-19 infection, demonstrating the need to treat both.

Design:

Three separate Phase III Clinical Trials were conducted by Cellular Sciences (the research arm of EmphyCorp Inc.) with COVID-19 infected Patients, Long COVID (Long Haulers) Patients, and in Patients with Pulmonary Fibrosis to determine the efficacy of N115, a sodium pyruvate based Nasal Spray. Patient symptoms, vital signs and respiratory function were evaluated compared to a placebo control or a no treatment baseline control.

Findings:

During active COVID-19 infection, N115 decreased viral titers and produced a statistically significant improvement over saline in coughing/sneezing and fatigue. N115 lowered viral titers to below 10,000 by day 6.4 versus day 7.7 for saline, versus 10.4 days for untreated controls.

As titers below 10,000 reduce the transmission of COVID-19, this may help decrease virus spread in N115 treated patients.

In Long COVID Patients, N115 produced statistically and clinically significant improvements to reduce, headaches, coughing/sneezing and increased SaO₂ levels (decreased hypoxemia) and improved breathing (dyspnea).

In Patients with Pulmonary Fibrosis, there was a significant improvement in all lung functions, compared to baseline, as determined by changes in SaO₂, FVC, FEV₁, PEF, and FEV₁/FVC ratio.

Conclusions:

N115 is safe and effective at reducing symptoms of active COVID-19 infection and improves disease condition in Long COVID patients.

Furthermore, N115 significantly improves lung function in Pulmonary Fibrosis Patients.

As COVID-19 and Pulmonary Fibrosis are associated with each other, our clinical research demonstrates that N115 is a promising treatment for both and adds to the current 19 human clinical trials where N115 has shown efficacy in thousands of patients, regardless of the etiology of the lung disease (COPD, CF, Allergic Rhinitis, Sinusitis, Flu, COVID-19 infected patients, Long COVID and Patients with Pulmonary Fibrosis).

Clinical Trials Results for COVID-19, Long COVID, and Flu are on [ClinicalTrials.Gov](https://clinicaltrials.gov):

N115 Nasal Spray Phase III Clinical Trial - Effects of Sodium Pyruvate Nasal Spray in COVID-19 Long Haulers (Long COVID)

<https://clinicaltrials.gov/ct2/show/NCT04871815?term=cellular+sciences&draw=2&rank=2>

N115 Nasal Spray Phase III Clinical Trials - Sodium Pyruvate Nasal Spray Treatment of COVID-19 and Influenza Infections

<https://clinicaltrials.gov/ct2/show/NCT04824365?term=cellular+sciences&draw=2&rank=1>