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University of Tokyo,
Graduate School of Pharmaceutical Sciences,
Chair of IT Healthcare Social Collaboration
neopharma Japan Co., Ltd.

Confirmation of Improved Recovery Rates from Sequelae of Novel Coronavirus by Means of Continuous 5-Aminolevulinic Acid (5-ALA) Intake

The Chair of the IT Healthcare Social Collaboration, Graduate School of Pharmaceutical Sciences, University of Tokyo*¹ (hereinafter referred to as 'Specially Appointed Professor Kyoko Imamura, ITHC Chair'), in association with neopharma Japan Co., Ltd.*² (hereinafter referred to as 'NPJ'), today announced that they have confirmed that group of patient with symptoms relating to post-infection novel coronavirus sequelae (hereinafter referred to as 'COVID-19 sequelae') showed improved recovery rates in terms of fatigue, anxiety and depression before and after ingesting specific doses of 5-aminolevulinic acid phosphate*³ (hereinafter referred to as '5-ALA') and sodium ferrous citrate (hereinafter referred to as 'SFC'). This follows the conduction of a safety test of 5-ALA phosphate and SFC at the Tokyo Centre on patients with COVID-19 sequelae,

This research was published in the journal 'ALA-Porphyrin Science' on March 24th, 2022 (JST).

[URL]

https://porphyrin-ala.com/wp-content/uploads/2021_2.pdf

[Research Topics]

- Patients suffering from COVID-19 sequelae took a daily dosage of 6 capsules containing 5-ALA phosphate (50 mg) and SFC (29 mg) for 28 consecutive days, with the safety of said capsules being confirmed at the end of the 28-day period.

- Patients suffering from COVID-19 sequelae who continuously ingested 5-ALA phosphate and SFC demonstrate a statistically significant rate of recovery in terms of fatigue, anxiety, and depression before and after consuming the examined dosage.
- Behavioral monitoring which uses Smart devices has been shown to be quite useful for the purposes of remote clinical research.

[Outline]

Since the beginning of the COVID 19 pandemic in 2020, while most infections have been shown to improve within a few weeks, there have been cases where sequelae have persisted for a much longer period, with a great variety in their symptoms. In the UK, it was reported that 1.5 million people were suffering from some form of COVID-19 sequelae at the end of January 2022*4. In Japan, the number of cases suffering from COVID-19 sequelae, mostly fatigue, is rising, and this is increasingly recognized as a new social issue.

Previous studies have demonstrated that 5-ALA phosphate together with SFC is effective at reducing fatigue levels in normal subjects. Based on the findings of these previous studies, there were concerns that patients with COVID-19 sequelae may engage in overconsumption of similar commercial products, so we decided to conduct a safety test targeting such individuals.

In this study we observed 21 patients with COVID-19 sequelae as they ingested capsules containing 5-ALA phosphate (300mg) and SFC (174mg) daily for 28 consecutive days in order to judge the safety of said capsules. We also measured the biometric status of their health using smart-watch and smartphone devices to explore the possibility of identifying any changes due to COVID-19 sequelae.

As a result, we were able to confirm 5-ALA/SFC was safely used in the examined dosage by patients with Covid-19 sequelae. Despite the limited number of target participants, statistically significant changes were observed in the levels of fatigue, anxiety, and depression before and after the consumption of the examined dosage.

As the rapid spread of the Omicron variant leads to increasing numbers of patients with COVID-19 sequelae, we believe it will become necessary to conduct further studies with larger sample sizes and variable ranges of dosage levels.

[Paper Title & Authors]

Title:

Phase 2 randomized clinical trial of 5-Aminolevulinic acid plus sodium citrate chloride vs placebo for Covid-19 infected patients recovered with sequelae

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[Glossary]

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The Chair of IT Healthcare Social Collaboration, in the Graduate School of Pharmaceutical Sciences, University of Tokyo was established in November 2018 with the aim of conducting collaborative research for medical development and innovation through the appropriate utilization of ICT. Their goal is to establish data reliability regulatory sciences necessary for conducting home / remote clinical trials; systemize the ICT education and medication information needed for pharmacy pharmacists; and create educational programs to foster leadership that promotes patient-centered drug development, as well as to realize real-world data analysis and clinical epidemiology / medical innovation. All of these will contribute to the ultimate goal of improving quality of life, longevity and all aspects of medical care for all people.

<https://plaza.umin.ac.jp/ithc-utokyo/>

*2 neopharma Japan Co., Ltd.

neopharma Japan was established as a joint venture between Neopharma LLC, based in the United Arab Emirates (UAE) and neoALA Co., Ltd (formally known as COSMO ALA Co.,

Ltd). The Neopharma Group is an international pharmaceutical company headquartered in the United Arab Emirates (UAE), which is developing its pharmaceutical manufacturing and sales business mainly in the Middle East and other developing nations. neopharma Japan plays a key role in Neopharma LLC's overseas strategy within the area of pharmaceutical manufacturing. Furthermore, neopharma Japan is creating new added value for the Group as a whole by promoting research and development of various applications of 5-amino-levulinic acid (5-ALA)

<https://www.neopharmajp.co.jp/>

^{*3} 5-Aminolevulinic Acid (5-ALA) Phosphate

According to a 2013 Ministry of Health, Labor and Welfare report on Food Materials, '5-aminolevulinic acid phosphate (produced by photosynthetic bacteria (Rhodobacter cephaloides))' is 'an ingredient substance that is not exclusively considered as a pharmaceutical drug unless it should claim to have pharmaceutical effects'. Our Company manufactures and sells 5-Aminolevulinic Acid in compliance with this report and the Food Sanitation Law.

<http://5ala-journal.com/>

^{*4} Reported issued by UK Office for National Statistics, 2nd March 2022

“Prevalence of ongoing symptoms following coronavirus (COVID-19) infection in the UK : 3 March 2022”

<https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/prevalenceofongoingsymptomsfollowingcoronaviruscovid19infectionintheuk/3march2022>

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