**Safety and immune-supportive potential of food supplement 5-amionolevulinic acid phosphate in coronavirus disease 2019: An open-lable, non-randomized pilot study**

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 **Ethical Approval**

This open-label, interventional, and exploratory pilot study was approved by the ethical committees of the Bahrain Defense Hospital, National Health Regulatory Authority and COVID-19 Committee of Bahrain. This study was conducted following good clinical practice and in accordance with the guidelines of the Declaration of Helsinki. All patients provided written informed consent. Data integrity and quality were regularly checked by a clinical monitor during on-site monitoring visits.

**Trial Registration**: The study was registered on ClinicalTrials.gov (https://clinicaltrials.gov/) on September 06, 2020 (registration no. NCT04542850).

**Competing Interests**

Andrea Ebeling, Riyadh Rehani, Marcus Stocker, and Norbert Berenzen are employees of photonamic GmbH and Co. KG. However, none of these authors have further financial arrangements (e.g., consultancies, stock ownership, equity interests, patent-licensing arrangements, research support, or major honorary). Motowo Nakajima is an employee of SBI Holdings and a shareholder of SBI ALA Pharma Japan; the study product was provided by SBI Pharmaceuticals, which is part of SBI Holdings. Walter Stummer is a consultant for SBI ALA Pharma and receives fees for consultancy. The remaining authors declare no conflicts of interest.

**Author Contributions**

Motowo Nakajima, Andrea Ebeling, Riyadh Rehani, Walter Stummer, Marcus Stocker, Norbert Berenzen, and Stephen Atkin designed and supervised the study. Abdulla Darwish and Abdulrahman Almadani were investigators at BDF Hospital, Jameela Alsalman was an investigator at Salmaniya Medical Complex. Mariam Murad was responsible for project administration. Riyadh Rehani, Stephen Atkin, and Norbert Berenzen wrote the manuscript. Norbert Berenzen was primarily responsible for final content and editing. All the authors have read and approved the final version of this manuscript.

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