

July 26, 2023

SBI Pharmaceuticals Co., Ltd.

Announces Publication of Research Paper on 5-ALA phosphate for Sarcopenia

SBI Pharmaceuticals Co., Ltd., (Head office: Minato-ku, Tokyo; Representative Director & President: Yoshitaka Kitao), a subsidiary of SBI Holdings, Inc., engaged in the research and development of pharmaceuticals and medical devices regarding 5-aminolevulinic acid (5-ALA) (*1), provided 5-ALA phosphate (*2) and ferrous citrate (SFC) (*3) to Juntendo University Graduate School (Location: Bunkyo-ku, Tokyo; President: Hajime Arai) and the specified clinical trial for Sarcopenia (principal investigators: Hiroataka Watada and Yoshifumi Tamura) was conducted. The article entitled "Efficacy and Safety of 5-ALA and SFC on Skeletal Muscle Index and Physical Function in Patients with Sarcopenia: A Multicenter, Double-Blind, Randomized, Controlled Trial (ALADDIN Study)" was published in the international scientific journal "Nutrients".

Journal	:	Nutrients 2023, 15(13), 2866
Title	:	Efficacy and Safety of 5-Aminolevulinic Acid Combined with Iron on Skeletal Muscle Mass Index and Physical Performance of Patients with Sarcopenia: A Multicenter, Double-Blinded, Randomized-Controlled Trial (ALADDIN Study)
author	:	Yoshifumi Tamura (Department of Sports Medicine and Sportology, Graduate School of Medicine, Juntendo University) et al.
URL	:	https://www.mdpi.com/2072-6643/15/13/2866
Abstract	:	Sarcopenia is a geriatric syndrome characterized by decreased physical performance, muscle mass, and strength. Since the intake of 5-ALA with iron can increase muscle mass and mitochondria in mice and elevate physical exercise performance in humans, the beneficial effects of 5-ALA in patients with sarcopenia are expected, but this remains unexplored in the literature. This study aimed to assess the efficacy and dose dependency of 5-ALA combined with iron in sarcopenia by measuring skeletal muscle mass index (SMI). Subjects with sarcopenia were enrolled and randomized into the 5-ALA and sodium ferrous citrate (SFC) intake groups (5-ALA50/SFC29, 5-ALA100/SFC29, 5-ALA150/SFC29, 5-ALA 100/SFC57, and 5-ALA0/SFC29 placebo) and ingested the assigned study food for 12 weeks. The primary endpoint, the change in SMI from baseline to week 12, did not differ significantly between the groups. Hand grip significantly increased or tended to increase from baseline after 12 weeks with all doses of 5-ALA or SFC compared with the placebo group. No consistent

changes were observed in the other endpoints, including calf circumference, physical function, or quality of life (QOL). Although this study suggests safe administration and the possibility of 5-ALA improving hand grip strength in patients with sarcopenia, further investigation is required.

(*1) 5-aminolevulinic acid: An amino acid produced in mitochondria. It is an important substance that serves as a functional molecule related to energy production in the form of heme and cytochromes, and its productivity is known to decrease with age. 5-aminolevulinic acid is contained in food such as shochu lees, red wine and Asian ginseng. It is also known as a material forming chloroplasts in plants.

(*2) 5-aminolevulinic acid phosphate has been added to the Ministry of Health, Labour and Welfare (MHLW) "Ingredients that are not deemed to be pharmaceuticals unless they are labelled as having pharmaceutical efficacies". It is not a pharmaceutical ingredient.

(*3) 5-ALA phosphate with SFC is not an approved drug. This new release is an introduction to the research paper and does not constitute a recommendation for the use of unapproved drug.

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