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Keio University School of Medicine

The World's First Human Clinical Study of the Age-Regulating Compound Nicotinamide Mononucleotide

A research group comprising Keio University School of Medicine's Department of Nephrology, Endocrinology and Metabolism, Department of Ophthalmology, and Department of Pharmacology, together with researchers at Washington University School of Medicine in St. Louis has initiated the world's first clinical study of the administration in humans of nicotinamide mononucleotide (NMN), a compound thought to regulate aging.

Previous studies have demonstrated that administration of NMN in animals increases nicotinamide adenine dinucleotide (NAD) levels in various organs, ameliorating the symptoms of age-related diseases. However, the safety and efficacy of NMN have not yet been assessed in humans. The purpose of this clinical study is to assess the safety of NMN in humans and clarify the mechanisms by which NMN contributes to NAD synthesis. The ultimate aim of studying the safety and pharmacokinetics of NMN in humans is to uncover ways to treat, or preferably prevent, age-related diseases in the future.

1. Background and Outline of the Research

On November 20, 2015, Keio University School of Medicine and Washington University School of Medicine in St. Louis, a leader in the field of NMN research, signed a five-year academic cooperation agreement to promote collaborative research in the areas of aging, longevity, and metabolic disease. Through close mutual collaboration and cooperation, the agreement aims to build a platform for advanced international research in these areas, contribute to scientific and technological progress, and find ways to reduce the impact of age-related diseases in aging societies.

To respond to the aging of populations worldwide, the research group has been undertaking various interdisciplinary approaches to prevent age-related diseases. Recent studies have shown that NAD levels decline in various organs with age, which leads to the development of such diseases as type 2 diabetes. It has already been demonstrated that enhancing NAD synthesis boosts the activity of sirtuins¹, enzymes linked to aging and longevity control in mammals, and that NMN is a precursor of NAD. However, the effects of NMN on human organs have not so far been evaluated.

This new research project, led by Prof. Hiroshi Itoh as the principal investigator with Prof. Kazuo Tsubota and Prof. Masato Yasui as co-investigators, will determine the safety and pharmacokinetics of NMN in humans. The project was originally conceived by Prof. Shin-ichiro Imai of Washington University School of Medicine in St. Louis, who is also involved in executing the research plan. For the study, ten healthy male adults aged between 40 and 60 will be given different doses of NMN over a fixed period of time. The investigators will monitor the participants through physiological tests and blood tests to assess the pharmacokinetics of NMN in humans.

2. Future Prospects

Evaluation of the pharmacokinetics of NMN and confirmation of the safety of administering it to humans will provide a scientific foundation for further clinical studies aimed at promoting dietary and nutritional approaches to the prevention and treatment of age-related diseases. The primary objective of this clinical study, however, is not to test NMN as a potential pharmaceutical drug, but to gain a thorough scientific understanding of the compound. Keio University and Keio University Hospital are not directly recruiting any study subjects.

3. Special Notes

This study is being conducted with the cooperation of the Longevity Initiative (led by Prof. Hideyuki Okano, Dean of Keio University School of Medicine) and is funded by Research Grants for Global Initiative Research Projects, an internal Keio research grant program promoting three transdisciplinary research and education initiatives (Longevity, Security, and Creativity) that Keio is currently focusing on as part of the Top Global University Project.

Terminology

¹Sirtuins are a family of NAD-dependent protein deacylases that have been demonstrated to regulate a wide variety of key cellular processes and control aging and longevity in diverse organisms.

*Please direct any requests or inquiries to the contacts listed below.

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