

Safety and Efficacy of NEXT-II[®], a Novel Water-Soluble, Undenatured Type II Collagen in Healthy Human Subjects Suffering from Occasional Knee Joint Pain

Orie Yoshinari,¹ Hiroyoshi Moriyama,² Yoshiaki Shiojima,¹ Hiromi Miyawaki³

¹Ryusendo Co., Ltd., 1-5-3, Nishi-ikebukuro, Toshima-ku, Tokyo 171-0021 Japan; ²The Japanese Institute for Health Food Standards, 6-26-12 Hongo, Bunkyo-ku, Tokyo 113-003, Japan;

³Miyawaki Orthopedic Hospital, Kita9, Nishi3, Kita-ku, Sapporo, Hokkaido 060-0809 Japan

Corresponding Author: Orie Yoshinari, Ph.D, Ryusendo, Co., Ltd.

Submission Date: June 8, 2015, Acceptance date: July 28, 2015: Publication date: July 31, 2015

ABSTRACT

Background and aim: Oral administration of a novel water-soluble undenatured type II collagen (NEXT-II[®]) has been demonstrated to ameliorate the signs and symptoms of rheumatoid arthritis (RA) in animal models. In the present investigation, we conducted a pilot study to examine the efficacy and safety of NEXT-II[®] in borderline subjects defined as healthy and non-diseased state, but with potential risks in knee joint health.

Method: We employed Western Ontario McMaster Index (WOMAC) score and Visual Analog Scale (VAS) scores to assess the extent of improvement in the knee joints in these volunteers following supplementation of 40 mg NEXT-II[®] (10 mg as undenatured type II collagen) over a period of 12 weeks.

Result: The results demonstrated that NEXT-II[®] treatment significantly reduced WOMAC and VAS scores compared to subjects at baseline. Specifically, in the evaluation using VAS, the borderline subjects at resting, walking, and going up and down the stairs revealed significant improvement when compared to the baseline.

Conclusion: The results of the studies demonstrated that NEXT-II[®] might be an ingredient which is safe and effective in the application of dietary supplement in ameliorating joint pain and

symptoms of the borderline subjects without any adverse events.