

Introduction/Abstract of Studies of Lyprinol on Arthritis

Efficacy and tolerability of mussel-Lyprinol® omega-3-complex on inflammatory rheumatoid disorders

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This 12 week drug monitoring study evaluated the effects of Sanhelios mussel-Lyprinol® omega-3-complex, on 50 adult men and women suffering from inflammatory rheumatoid arthritis. 34 of the 50 patients required medicinal treatment before and during the study. Upon completion of the study, for 21 of the 34 subjects (64 %) current drug therapy could be reduced or terminated. 13 of those did not even require further therapy. At the end of the treatment period, 38 % of all subjects were regarded as being free from disorders and the number of subjects suffering from severe pain was significantly decreased from 60% (at baseline) to 25 % (at completion of the trial). A significant positive effect was observed for all investigated parameters. Sanhelios mussel-Lyprinol® omega-3-complex was generally very well tolerated, with only one, non-serious adverse event (mild nausea) observed, which can probably be related to the study medication. Sanhelios mussel-Lyprinol® omega-3-complex , therefore, proved to be an effective and very well tolerated dietary supplement for the treatment of inflammatory rheumatoid arthritis.

Anti-inflammatory effects of a stabilized lipid extract of *Perna canaliculus* (Lyprinol®)

Author: Georges M. Halpern 11, M.D., Ph.D., D.Sc.

The Maoris who live in New Zealand have claimed for centuries that consuming local green-lipped mussels helps them maintain good health. Recent statistics show that the reported incidence of arthritis is extremely low in the coastal-dwelling Maoris, who consume large amounts of green-lipped mussels, whereas Maoris who reside in the interior have the same incidence of arthritis as New Zealanders of European origin. To investigate its reported anti-inflammatory activity, researchers in the United Kingdom, Australia and Japan have studied the effects of various oral preparations of the New Zealand green lipped mussel, *Perna canaliculus*.

Clinical studies since 1980 have shown that a stabilized lipid extract of *Perna canaliculus* is effective in relieving symptoms of rheumatoid arthritis and osteoarthritis. This extract exhibits significant anti-inflammatory effects and has been shown to down-regulate the lipoxygenase pathways responsible for production of pro-inflammatory leukotrienes and other eicosanoids. This article reviews recent research on green lipped mussel extracts as well as technical issues surrounding the development of stable mussel preparations.

Marine lipid extract benefits OA patients

Author: Prof. Chak Sing Lau

The first double-blind, placebo-controlled clinical trial of Lyprinol® in patients with osteoarthritis (OA) has confirmed its effectiveness in treating the pain associated with the disease and improving mobility. Lyprinol® is a purified marine lipid extract from New Zealand's green-lipped mussel (*Perna canaliculus*), consisting of a unique patented combination of lipids and polyunsaturated fatty acids with a high omega-3 to omega-6 ratio. The study was conducted between 2001 and 2003 by a team of researchers at Queen Mary Hospital, led by Professor Chak Sing Lau of the Division of Rheumatology, The University of Hong Kong [Progress in Nutrition, in press]. Eighty patients with OA of the knee were randomized to receive either Lyprinol® or placebo for six months. Patients were allowed to take rescue analgesics (acetaminophen), but no other arthritis medications, and were followed-up at 2, 4, 8, 12 and 24 weeks for arthritis assessment and safety evaluation.

The assessment was based on a 100mm visual analog scale (VAS) for pain, validated Chinese version of the Oxford Knee score (COKS), validated Chinese version of the Arthritis Impact Measurement Scale 2-short form (CAIMS2-SF), patient's and physician's global assessment of arthritis, and erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) tests.

According to Lau, there was a greater improvement in the perception of pain as measured by the VAS, and in patients' global assessment of arthritis, in subjects who took Lyprinol® compared with the placebo group.

Efficacy of lipid extract from *Perna canaliculus* in treatment of musculoskeletal diseases in old age

Authors: Marek Zawadzki, Jacek Szechirski, and Dariusz Koztowski

Osteoarthritis is a social disease that has a multi-factorial aetiology. It is the most common rheumatic disease characterised by pain and inflammation due to an

involvement of articular cartilage, bone and soft tissues. The prevalence of osteoarthritis increases with age and depends on the presence of risk factors.

We can distinguish primary osteoarthritis changes with unknown reason, greater incidence and secondary changes as a result of injury, the influence of metabolic factors, or congenital malformations.

Rheumatoid arthritis is a systemic, inflammatory and autoimmunologic connective tissue disorder of unknown origin. Rheumatoid arthritis has a chronic progressive character that leads to physical disability and even untimely death. Effective treatment requires quick and permanent limitation of the inflammatory process. In this paper we have examined the efficacy of anti-rheumatic drugs, especially Lyprinol. *Geriatrics* 2010; 4: 39-46.

Measurement of pain relief resulting from the administration of lipid complex PCSO-524™ as compared to fish oil for treating patients who suffer from osteoarthritis of knee and/or hip joints *Perna canaliculus*

Authors: Jacek Szechiński, Marek Zawadzki

Aim: To compare, from baseline, pain relief, changes in the indicators of quality of life and safety for osteoarthritis patients taking a patented CO₂ stabilised oil from the NZ Greenshell Mussel *Perna canaliculus* (PCSO-524™) compared with patients taking fish oil (containing an industry standard EPA 18% and DHA 12% blend).

Material and methods: 50 patients older than 50 years from the Rheumatology Clinic at the Wroclaw Medical University Hospital were administered randomly either Lyprinol® capsules that contained PCSO-524™ or fish oil capsules in a double-blind study. All subjects had a diagnosed history of osteoarthritis of the knee and/or the hip. The patients' characteristics are presented in Tables I and II. At baseline and then after four, eight and 12 weeks of treatment, information was collected using first the visual analogue scale (VAS) for pain; second the health assessment questionnaire (HAQ); and third the patient's own overall assessment of the progression of osteoarthritis and their health condition. For patient safety control, before enrolment in the study and at the end of the study, patients had a blood cell count, ESR, ALAT and urine analysis.

Results: Patients treated with PCSO-524™ showed a statistically significant improvement of both their pain symptoms related to osteoarthritis and improved quality of their daily lives ($p = 0.05$) (Tables III-IV, Fig. 1-2). No side effects were observed with the patients who took PCSO-524™. Patients treated with fish oil showed significantly less improvement and a greater level of physical discomfort caused by the fish oil during the study.

Conclusion: Reduction of pain was statistically evident at four weeks among the subjects who took capsules that contained PCSO-524™. Practitioners can expect

quicker long-term results with less risk of side effects for their osteoarthritis patients when they recommend products that contain PCSO-524™, compared with fish oil.

Perna canaliculus Lipid Complex PCSO-524™ Demonstrated Pain Relief for Osteoarthritis Patients Benchmarked against Fish Oil, a Randomized Trial, without Placebo Control

Authors: Marek Zawadzki, Claudia Janosch, and Jacek Szechinski

Osteoarthritis (OA) typically generates pain, reduced mobility and reduced quality of life. Most conventional treatments for osteoarthritis, such as non-steroidal anti-inflammatory drugs (NSAIDs) and simple analgesics, have side effects. PCSO-524™, a non polar lipid extract from the New Zealand Green Lipped Mussel, is rich in omega-3 fatty acids and has been shown to reduce inflammation in both animal studies and patient trials. This OA trial examined pain relief changes in relation to quality of life and safety of use for OA patients who took PCSO-524™ compared with patients who took fish oil (containing an industry standard EPA-18% and DHA-12% blend). PCSO-524™ patients showed a statistically significant improvement compared with patients who took fish oil. There was an 89% decrease in their pain symptoms and 91% reported an improved quality of life. Patients treated with fish oil showed significantly less improvement and a greater level of physical discomfort during the study. These results suggest that PCSO-524™ might offer a potential alternative complementary therapy with no side effects for OA patients.