

Marine lipid extract benefits OA patients



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 100 mm 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 erythrocite 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. After adjustment for the change in the amount of analgesics used between visits, the improvements became apparent from week 4. "This confirms previous open-label studies with Lyprinol[®], where patients reported that it took 3 to 4 weeks or more to notice a positive effect," he notes.

"In addition, after one month, patients on Lyprinol[®] but not on placebo had improved scores in the CAIMS2-SF physical function and psychological status domains," he says. There was also a tendency toward improvement in the majority of other efficacy parameters, although the difference between patients taking Lyprinol[®] and those on placebo did not





reach statistical significance.

Safety assessment involved enquiry about adverse drug reactions, whole blood count, liver function tests, serum urea and creatinine, and prothrombin and activated partial prothrombin times.

Lau says there were no serious adverse effects reported with Lyprinol[®] throughout the study period, and no significant difference in the incidence of adverse events or withdrawal from the study between the treatment and placebo groups.

Previous studies suggest that the anti-inflammatory effect of Lyprinol[®] was due to the inhibition of the 5-lipoxygenase and cyclo-oxygenase pathways, which resulted in reduced production of leukotrienes and prostaglandins. "Theoretically, it may be helpful in other conditions with an inflammatory component, such as rheumatoid arthritis or asthma," remarks Lau.

A double-blind, placebo-controlled trial demonstrated its benefits in controlling daytime wheeze in patients with atopic asthma [*Eur Respiratory J* 2002;20:596-600].

Lau emphasizes the importance of applying double-blind, placebo-controlled studies to experimental therapies, especially natural therapies where great placebo effects are expected.

"The trial provides evidence-based data supporting the use of Lyprinol[®] in the management of OA. Although it offers no cure, Lyprinol[®] can relieve symptoms in some patients with OA. Its effects are similar to those of anti-inflammatory drugs, with the advantage of a milder safety profile," he concludes.