

A combined phase I and II open label study on the effects of a seaweed extract nutrient complex on osteoarthritis

Authors: Stephen P Myers, Joan O'Connor, J Helen Fitton, et al.

**Published Date February 2010 , Volume 2010:4
Pages 33 - 44**

Stephen P Myers^{1,2}, Joan O'Connor^{1,2}, J Helen Fitton³, Lyndon Brooks⁴, Margaret Rolfe⁴, Paul Connellan⁵, Hans Wohlmuth^{2,5,6}, Phil A Cheras^{1,2}, Carol Morris⁵

¹NatMed-Research, ²Centre for Health and Wellbeing, ⁴Graduate Research College, ⁵Centre for Phytochemistry and Pharmacology, ⁶Medicinal Plant Herbarium, Southern Cross University, Lismore, NSW, Australia; ³Marinova Pty Ltd, Hobart, Tasmania, Australia



Background: Isolated fucoidans from brown marine algae have been shown to have a range of anti-inflammatory effects.

Purpose: This present study tested a Maritech[®] extract formulation, containing a blend of extracts from three different species of brown algae, plus nutrients in an open label combined phase I and II pilot scale study to determine both acute safety and efficacy in osteoarthritis of the knee.

Patients and methods: Participants (n = 12, five females [mean age, 62 ± 11.06 years] and seven males [mean age, 57.14 ± 9.20 years]) with a confirmed diagnosis of osteoarthritis of the knee were randomized to either 100 mg (n = 5) or 1000 mg (n = 7) of a Maritech[®] extract formulation per day. The formulation contained Maritech[®] seaweed extract containing *Fucus vesiculosus* (85% w/w), *Macrocystis pyrifera* (10% w/w) and *Laminaria japonica* (5% w/w) plus vitamin B6, zinc and manganese. Primary outcome was the average comprehensive arthritis test (COAT) score which is comprised of four sub-scales: pain, stiffness, difficulty with physical activity and overall symptom severity measured weekly. Safety measures included full blood count, serum lipids, liver function tests, urea, creatinine and electrolytes determined at baseline and week 12. All adverse events were recorded.

Results: Eleven participants completed 12 weeks and one completed 10 weeks of the study. Using a multilevel linear model, the average COAT score was reduced by 18% for the 100 mg treatment and 52% for the 1000 mg dose at the end of the study. There was a clear dose response

effect seen between the two treatments ($P \leq 0.0005$) on the average COAT score and each of the four COAT subscales (pain, stiffness, difficulty with physical activity and overall symptom severity) ($P \leq 0.05$). The preparation was well tolerated and the few adverse events were unlikely to be related to the study medication. There were no changes in blood parameters measured over the course of the study with the exception of an increase in serum albumin which was not clinically significant.

Conclusion: The seaweed extract nutrient complex when taken orally over twelve weeks decreased the symptoms of osteoarthritis in a dose-dependent manner. It was demonstrated to be safe to use over the study period at the doses tested. The efficacy of the preparation now needs to be demonstrated in a phase III randomized controlled trial (RCT).

Australian and New Zealand Clinical Trials Register: ACTRN12607000229471.

Keywords: fucoidan, osteoarthritis, complementary medicine, inflammation, TNF alpha