

中文題目：褐藻萃取物可以降低脂肪肝病人的血清丙氨酸氨基轉移酶 - 雙盲隨機分派對照試驗，期中報告

英文題目：FucoHiQ (Fucoidan and High-stability Fucoxanthin) Decreases Serum Alanine transaminase (ALT) in Patients With Non-alcoholic Fatty Liver Disease (NAFLD)-A Double Blind, Randomized Controlled Trial, An Interim Report

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Background : Nonalcoholic fatty liver disease (NAFLD) is one of the most common chronic liver diseases worldwide. Accompanied with the process of steatosis and chronic inflammation, NAFLD may potentially lead to more severe condition such as nonalcoholic steatohepatitis (NASH), cirrhosis, and eventually hepatocellular carcinoma.

Liver biopsy was still gold standard for diagnosis and evaluation of severity of NAFLD. Some studies have shown biomarkers such as total cholesterol, triglyceride, insulin resistance, ALT, and adiponectin offering a potential prognostic or diagnostic indicator for disease.

Brown seaweeds rich in flavonoids and bioactive polysaccharides have been shown the ability to modulate risk factors in obesity and related metabolic diseases. Fucoidan is a class of sulfated and fucosylated polysaccharides identified in brown seaweeds. Animal studies have proved the effective function of fucoidan in suppressing fat accumulation, oxidative stress, and inflammatory cytokines in the liver. Fucoxanthin, a carotenoid relative present in the chloroplasts of brown seaweeds, have also displayed strong anti-inflammatory activity through their antioxidant activities, however, there was no well-conducted clinical trial focusing on the effect of liver protection.

Aim : To investigate the hepatoprotective effects of oligo-fucoidan and high-stability fucoxanthin (HS-Fucox) on non-alcoholic fatty liver disease, as shown by the parameters of alanine aminotransferase, metabolic profiles and changes of hepatic steatosis/fibrosis.

Methods : Fifty-two patients with NAFLD confirmed by abdominal echography and

Fibroscan were enrolled. Patients with seafood allergy, taking Vitamin E, Pioglitazone or Liraglutide were excluded. Forty-eight patients were randomized into the treatment group with three FucoHiQ (275 mg Oligo Fucoidan + 275 mg HS Fucoxanthin) two times daily or the control group with placebo.

Both groups were implemented with a twenty four-week follow-up. The severity of fatty liver and liver fibrosis detected by FibroScan as well as the read-out of Creatine, AST, ALT and blood sugar were monitored every four weeks during the follow-up. Metabolic profiles such as adiponectin, leptin, HbA1c, and CRP were measured at the 1st, 4th, 12th, and 24th week during follow-up. This interim report was currently available by using the database of 12th week follow-up.

This study has been proved and registered at ClinicalTrials.gov with the number of NCT02875392.

Results : There were no significant differences in the statistics of baseline age, gender, BMI, ALT of both groups. A significant decrease of ALT is noted in the treatment group than in the control group ($p < 0.05$). We also noted that increasing adiponectin was moderately correlated with decreasing ALT ($r=0.31$). However, the severity of steatosis/fibrosis and other metabolic profiles had no significant difference in both groups.

Conclusion : In the interim report of this study, FucoHiQ (Fucoidan and High-stability Fucoxanthin) may reduce alanine aminotransferase (ALT) in patients with NAFLD which is associated with increasing adiponectin.