

中文題目：樟芝菌絲體營養補充劑應用於改善非酒精性脂肪變性肝炎(NASH)的隨機、雙盲臨床研究

英文題目: Clinical safety and beneficial effects of *Antrodia cinnamomea* mycelia in non-alcoholic steatosis hepatitis (NASH), randomized, double-blind clinical study

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Background: The nonalcoholic fatty liver disease (NAFLD) is a common disease which could further developing into nonalcoholic steatohepatitis (NASH), fibrosis and hepatocellular carcinoma. The *Antrodia cinnamomea* (*A.cinnamomea*; synonym: *Antrodia camphorata*) is a traditional medicinal fungus in Taiwan. It has been reported to have medicinal and pharmacological activities, including antitumor, anti-inflammatory, antioxidant, immunomodulatory, and hepatoprotective effects. In hepatoprotective effects, the studies indicated *Antrodia cinnamomea* mycelia (ACM) can reduce serum AST and ALT levels. The aim of this study will to investigate the clinical /antioxidant status and immunity effects of oral administration ACM in NASH patients. **Materials & Methods:** The 28 NASH subjects were double-blinded randomized divided into two groups: (1) placebo group: 13 patients received diet and exercise education but no oral administration ACM; (2) study group: 15 patients received diet /exercise education and oral administration ACM (1.8g /day). The duration of experiment is 24 months. The body weight, serum levels of AST, ALT, glucose, insulin, TG, cholesterol, FibroMax test, TNF- α , IL-6, IL-1 β and immune function will be examined. **Results:** In study group, the levels of AST, ALT, AC sugar, Ferritin and FibroMax index (hepatic steatosis and inflammation scores) reduced but the percentage of CD3⁺CD8⁺ cells increased during 0, 3 and 6 months significantly ($p < 0.05$). However, the levels of levels of AST, ALT, AC sugar, Ferritin and inflammation score reduced ($p < 0.05$) but hepatic steatosis score and CD3⁺CD8⁺ cells showed no difference significantly in placebo group during 0, 3 and 6 months. **Conclusion:** This study is the first study of *Antrodia cinnamomea* mycelia for NASH patients. The effects of *Antrodia cinnamomea* mycelia could reduce liver inflammation / steatosis and increased the percentage of CD3⁺CD8⁺ cells in NASH patients.