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Taipei Medical University
TMU-Joint Institutional Review Board

Protocol: Fucoidan Improves the Metabolic Profiles of Patients with Non-alcoholic Fatty Liver Disease (NAFLD)

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1. Study Protocol

In this study, a double-blind randomized experimental design was used to allow subjects to take six months of health supplements (experimental group) and six months of placebo (control group) to see their effects on fatty liver, liver fibrosis and metabolic indicators.

First ask the patient to agree to participate in the trial and fully understand the content of the project. After the eligible subjects are evaluated and confirmed to be able to participate in the trial, they will take health care products daily according to the research setting (3 tablets before breakfast, 3 tablets before dinner, total 6 tablets), at the first time of the test, 4 weeks, 8 weeks, 12 weeks, 16 weeks, and 24 weeks respectively to check blood and biochemical values, including creatinine (Cr), liver function index (AST, ALT), pre-meal blood sugar (AC) , And use Fibroscan to detect fatty liver and liver fibrosis. At the first time of the test, 4 weeks, 12 weeks, and 24 weeks, return to check blood routine / white blood cell classification examination (CBC/DC), uric acid (UA), cholesterol blood fat (HDL, LDL), triglyceride (TG), lipid Adiponectin/Leptin (Adiponectin/Leptin), C-reactive protein (CRP), insulin (Insulin); In addition, at the first, 12 weeks, and 24 weeks of the test, the metabolic indicators related to glycosylated hemoglobin (HbA1c) were tested.

This study will extract the follow-up data of subjects' return visits for analysis and research. The follow-up methods are phone reminders two weeks before the start of the trial, and reminders during monthly visits, asking about taking status, etc., to increase the subjects' compliance.

2. Study procedures

SCHEDULE OF EVENTS

Evaluation Procedure	Registration	First Time	Week 4	Week 8	Week 12	Week 16	Week 24
Informed Consent	V	A					
		B					
Assess Eligibility	V	A					
		B					
Blood inspect							
Cr、AST、ALT、AC		A	A	A	A	A	A
		B	B	B	B	B	B
CBC/DC、UA、HDL、LDL、TG、Adiponectin /leptin、CRP、Insulin		A	A		A		A
		B	B		B		B
HbA1c		A			A		A
		B			B		B
FibroScan		A	A	A	A	A	A
		B	B	B	B	B	B

3. Statistical Analysis Plan

This study is expected to include a total of 60 people with non-alcoholic fatty liver disease, divided into two groups, 30 people in each group, double-blind randomized test. The primary end point (primary end point) is to see the severity of changes in the patient's steatohepatitis and fibrosis. The secondary end point is the degree of change in the patient's weight and lipid profile. Continuous variables are presented in normal probability plots and Shapiro-Wilk test evaluation. The relationship between variables Connectivity is analyzed by Pearson's correlation, and the Intra-intervention comparison is performed by Paired t test. Unify The calculation software is based on R software version 2.11.1.