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Study Protocol

The Effect of *Ophiocephalus striatus* Extract on IGF-1 and IL-6 Levels in Elderly Patients with Sarcopenia

Trial Registration Number: NCT05869383

Date of document: 15 March 2023

Study Objective: To investigate the effects of *Ophiocephalus striatus* extract on insulin-like growth factor-1 serum, interleukin-6 serum levels, and sarcopenia-related parameters in older adults with sarcopenia.

Study Design:

- Double-blind, randomized controlled trial.
- 80 older adults with sarcopenia.
- Intervention: *Ophiocephalus striatus* extract or placebo for two weeks.
- Primary outcomes: IGF-1 serum and IL-6 serum levels.

Study Methods:

- **Participants:**
 - Inclusion criteria: Older adults (≥ 60 years old) with sarcopenia diagnosed using AWGS criteria.
 - Exclusion criteria: Patients with severe chronic liver disease, impaired kidney function, acute disease phase, malignancy, depression, history of hypersensitivity to *Ophiocephalus striatus*, or those who refused to participate.
- **Intervention:**
 - *Ophiocephalus striatus* extract (5 g twice daily) or placebo for 2 weeks.
 - Both groups received a tailored diet.
- **Data Collection:**
 - Sociodemographic information, comorbidities, physical examinations, anthropometric measurements, nutrition assessment, functional status assessment, mental status assessment, cognitive status assessment, sarcopenia screening, handgrip strength assessment, 6 m walk speed assessment, muscle mass assessment, laboratory tests for IGF-1 and IL-6.
- **Outcome Measures:**
 - Primary outcomes: IGF-1 and IL-6 serum levels.
 - Secondary outcomes: Calf circumference, appendicular skeletal muscle mass index (ASMI), handgrip strength, gait speed, creatinine levels.
- **Data Processing and Analysis:**
 - Descriptive and inferential statistics.
 - Paired t-tests, independent t-tests, Wilcoxon test, Mann-Whitney U tests.
 - p-value < 0.05 considered statistically significant.

Study Results:

- Significant reduction in serum IL-6 levels in the intervention group.
- Non-significant increase in IGF-1 levels in the intervention group.

- Improvements observed in calf circumference, ASMI, handgrip strength, and gait speed in the intervention group.

Study Conclusions:

- *Ophiocephalus striatus* extract positively impacts serum IL-6 levels in older adults with sarcopenia.
- The study suggests that *Ophiocephalus striatus* extract may offer a valuable intervention for managing sarcopenia.

Additional Notes:

- The study was conducted at the Geriatric Clinic of RSUP Dr. Mohammad Hoesin, Palembang.
- Ethical clearance was obtained from the Research Ethics Commission (No. DP.04.03/D.XVIII.6.11/ETIK/36/2023).
- The study was conducted from March 2023 to August 2023.