

COVER PAGE

Inform Consent

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

INFORMED CONSENT FORM IN RESEARCH		
Researcher	dr. Nur Riviari, SpPD, K-Ger	
Information provider	dr. Nur Riviari, SpPD, K-Ger	
Information recipient		Date
Type of information	Content of Information	Mark
Research title	The Effect of Ophiocephalus striatus Extract on IGF-1 and IL-6 Levels in Elderly Patients with Sarcopenia	
Research objectives	To determine the effect of Ophiocephalus striatus on IGF-1 and IL-6 levels in elderly patients with sarcopenia.	
Research methodology	<p>Research Focus: This research is a clinical trial of a drug. Several aspects to be observed in this research include nutritional status measured through IGF-1 and IL-6 levels.</p> <p>Research Procedure: The research will be conducted at the Geriatrics and Internal Medicine Clinic, RSUP Dr. Mohammad Hoesin, Palembang. Interviews, physical examinations, and blood tests will be conducted before and after the administration of the tested supplement to collect the required data.</p> <p>The physician will explain the background, purpose, and procedures of this clinical trial and inquire about the willingness to participate. If willing, participants will undergo subject selection involving interviews, physical examinations, and laboratory tests (which may also refer to medical records). If the tests do not reveal significant liver and/or kidney function disorders, participants will be asked to consent to participate in this clinical trial. They will be given the tested supplement to consume for 2 weeks. After 2 weeks, participants will be re-interviewed, and blood samples will be taken again.</p>	

Research risks	Participants may experience mild discomfort or pain during blood collection, occasionally accompanied by slight bruising, which will fade within a few days. Rarely, allergic reactions may occur.	
Research benefits	By participating in this research, participants contribute valuable scientific information about the effects of <i>Ophiocephalus striatus</i> (snakehead fish) extract, particularly whether it can improve sarcopenia conditions in the elderly.	
Alternative procedures	There are no alternative procedures.	
Confidentiality of data	All information obtained during this research, including personal and research data, will be kept confidential. The participant's name or any documents identifying them as part of the research will not be disclosed without their consent.	
Compensation in case of side effects	Any significant incidents, such as hospitalization or death, must be reported to the researcher via phone. Participants experiencing complaints can contact the researcher 24/7 by phone. Participants reporting side effects will be asked to come for further anamnesis, physical examination, and laboratory tests as indicated.	
Researcher's Name and Address	Dr. Nur Riviati, SpPD, K-Ger Jl. DR. Hakim No. 1120, Sei Pangeran, Ilir Timur I, Palembang	
Number of subjects	80	
Potential hazards	Allergic reactions to <i>Ophiocephalus striatus</i> extract	
Cost incurred	In case of significant side effects	
Incentives for participants	Light refreshments	
I hereby state that I have explained the above matters truthfully and provided an opportunity for questions and/or discussions.	Researcher's signature	
I hereby state that I have received the information as mentioned above, which I have marked/initialed in the respective column, and I understand it.	Participant's signature	