PART 1: Administrative Details	
Full Study Title	Application of Bioactive Peptides for the attenuation of malnutrition in cancer patients in a treatment health facility in Ghana
Protocol/ Document Number	Version 5 dated 1st May 2024
Date of Receipt of the Application	17th May 2023
Phase of Study	Phase II
Study Registration Details	**PACTR20220585571226** Clinical trial approval certificate no. **FDA/CT/245**
Name and Address of Applicant(s)	Prof. Christiana Nsiah-Asamoah Principal Investigator Department of Clinical Nutrition and Dietetics University of Cape Coast Email: cbuxton@ucc.edu.gh Tel.: 0249943297
Name and Address of Sponsor(s)	South China University of Technology. Lin Wensha, School of Food Science and Engineering, 381 Wusha Road, Tianhe District, Guangzhou, China Tel: +86-18826223801 Email: linwensha@scut.edu.cn
Name and Address of Principal Investigator(s)	Prof. Christiana Nsiah-Asamoah Principal Investigator Department of Clinical Nutrition and Dietetics University of Cape Coast Email: cbuxton@ucc.edu.gh Tel.: 0249943297
Study Sites	Cape Coast Teaching Hospital (CCTH) Cancer Unit
Study Duration	12 months
FAPAR Number	FDA/CT/PAR/CTA/248

PART 2: Investigational Product(s)	
Name of Investigational Product(s) including Comparator(s).	• Vegalbum small molecular protein peptide (soy peptide) • Nutrition education on dietary modifications (as part of standard of care)
Justification of Investigational Product(s) including comparators	Plant-derived peptides have increasingly become of interest in human health due to their antioxidant, antihypertensive, and anticancer potential. Recent studies suggest that soybean protein could be effective in attenuating muscle wasting in cancer patients by modulating protein synthesis and proteolysis. Due to the shortcomings in the development of soybean protein supplements, such as their solubility and absorption, soybean protein, derived peptides have shown to be easier to digest, and have high solubility, hence their use in this study to assess ability to reduce malnutrition in cancer patients.

PART 3: Study Summary

Study Objectives

The aims of this study are:
(1) to evaluate the efficacy of food-borne (soybean) peptides in reducing malnutrition in cancer patients.

(2) the secondary objective is to assess the impact of the peptides on hemoglobin levels, kidney function, liver function, and C-reactive protein levels in cancer patients.

Study Design

A phase II randomized controlled trial with two groups will be used for the study. Eligible patients with newly diagnosed primary tumors (such as colorectal cancer, breast cancer, gastrointestinal tumor, hematological system tumor, etc.) receiving care at the Cape Coast Teaching Hospital (CCTH), Cape Coast will be randomly assigned to either a control group (receive nutrition education on dietary modifications) or an experimental group (receive soy peptide group plus nutrition education on dietary modifications) for 16 weeks with follow up visits scheduled for Weeks 0, 4, 8, 12, and 16. Data collection will involve the use of a QoL questionnaire, anthropometric measurements, and laboratory assessments.

PART 3: Study Summary

Eligibility Criteria

Inclusion criteria

Patients who meet all of the following criteria will be eligible to be included in the study:

1. Histological confirmation of a newly diagnosed primary tumor (duration of the tumor: stages 1 to 3)

2. Patients with a BMI between 12 to 17.9 kg/m^2

3. Subjects aged 30 years and above

4. Patients classified as being malnourished according to the patient-generated subjective global assessment (PG-SGA)

5. Non-pregnant and non-lactating women

6. Nutritional assessment results before chemotherapy showing malnutrition

7. Ability to voluntarily complete the informed consent process.

Exclusion criteria

Patients who meet any of the following criteria shall not be admitted to the study:

1. Frequent vomiting or conditions affecting oral administration (e.g., the patient has intestinal obstruction)

2. Pregnant or lactating women (all women, except those in the menopausal period, will undergo a pregnancy test to assess their eligibility before being included in the study)

3. Subjects with other serious illness, mental and physical disability

4. Subjects identified to be on any form of dietary intervention program including the regular intake of nutritional supplements and probiotics.

Sex of participants

Male and Female

PART 3: Study Summary

Age Boundaries

Subjects aged 30 years and above

Date of Commencement (Expected or Actual)

Expected date of commencement: 24th June 2024

Status of Study

Not yet commenced

PART 4: Scientific Discussion

Summary of Review Comments

Quality

The quality of the Investigational product, Vegalbum small molecular protein peptide has been assessed by the FDA. The applicant submitted the following documents which were reviewed and found satisfactory to fulfill the quality requirement of the trial:

1. Signed Investigational Medicinal Product Dossier (IMPD) for Soypeptide Product Version 5 dated 1st May 2024
2. Food Safety System Certificate for Guangzhou Peprolife Biotechnology Co. Ltd. Issued by the China Quality Certification Centre on 22nd February 2021 and valid till 21st February 2024.
3. Quality Management System Certificate for Guangzhou Peprolife Biotechnology Co. Ltd. Issued by the China Quality Certification Centre on 19th December 2023 valid until 18th December 2026
4. HACCP Systems Certificate for Guangzhou Peprolife Biotechnology Co. Ltd. Issued by the China Quality Certification Centre on 20th November 2023 and valid until 19th November 2026
5. CoAs for the Batches of The IPs Intended to Be Imported for The Study (Test Result).

Safety

The following documents were reviewed and found satisfactory to fulfill the safety requirement of the trial:

1. Benefit/Risk Assessment Report provided in the approved protocol.

PART 4: Scientific Discussion

2. Signed Investigator's brochure (IB) - Version 5 dated 1st May 2024

Efficacy

Evaluation of the possible efficacy of the intervention was based on the information stated in the protocol as part of the objectives which are:

1. To evaluate the efficacy of food-borne (soybean) peptides in reducing malnutrition in cancer patients.
2. The secondary objective is to assess the impact of the peptides on hemoglobin levels, kidney function, liver function and C-reactive protein levels in cancer patients.

The applicant submitted the following documents which were reviewed and found satisfactory to fulfill the efficacy requirement of the trial:

1. Signed study protocol Version 5 dated 1st May 2024.
2. Signed Investigator's brochure (IB)- Version 5 dated 1st May 2024

Overall Comments

After initial review, the application was deferred with queries to be addressed by the applicant. Following the satisfactory response to all queries on the submission, the study was approved and issued a clinical trial certificate.

The applicant is committed to ensuring that the study is conducted in compliance with Good Clinical Practice (GCP) and applicable regulatory requirements.

All participants will consent to the protocol prior to participation in any study-related activity.

Based on the assessment of medical and ethical principles, the anticipated benefits to the participant justify the foreseeable risks and inconveniences related to the conduct study.

PART 5: Application Review Process

The routine pathway was used. The application was reviewed under the routine approval pathway within 36 working days.

PART 6: Status after Review

The application was approved on 12th June 2024

REFERENCES

1. Approved and signed study protocol Version 5 dated 1st May 2024.
2. Clinical trial study participant informed consent form version 5 dated 1st May 2024.
3. Benefit/Risk Assessment Report.
4. Signed Investigator's brochure (IB)- Version 5 dated 1st May 2024
5. Signed Investigational Medicinal Product Dossier (IMPD) for Soy peptide Product Version 5 dated 1st May 2024
6. FDA's Clinical Trial Assessment form version for Clinical Trial Application version 1.0 dated 2nd September 2019
7. Guidelines for Authorization of Clinical Trials of Medicines, Food Supplements, Vaccines and Medical Devices in Ghana
8. Guidelines for Good Clinical Practice in Ghana