Informed Consent Form

Project Title: The Effect of Peri-Transplant Oral Use of Food for Special Medical Purposes on Nutrition and Intestinal Function in Patients Undergoing Hematopoietic Stem Cell Transplantation

Protocol Version Number and Date: V1.0, 2022.3.8
NCT Number: NCT05460013
Informed Consent Form Version Number and Date: V1.1, 2022.3.8

(The uploaded consent form is the latest version that has been reviewed by Human Subjects Protection)

Dear Patient:

We invite you to participate in the research study titled "**The Effect of Peri-Transplant Oral Use of Food for Special Medical Purposes on Nutrition and Intestinal Function in Patients Undergoing Hematopoietic Stem Cell Transplantation**," which has been approved by Renji Hospital, Shanghai Jiao Tong University School of Medicine. This study will be conducted at **Renji Hospital, Shanghai Jiao Tong University School of Medicine**, and it is expected that **100** subjects will voluntarily participate. This study has been reviewed and approved by the Ethics Committee of Renji Hospital, Shanghai Jiao Tong University School of Medicine.

This document provides you with information to help you decide whether to participate in this clinical study. Your participation is entirely voluntary, and your decision will not affect your normal medical care rights and treatment at this hospital. Please be assured! If you choose to participate, our research team will make every effort to ensure your safety and rights throughout the study.

Please read this document carefully. If you have any questions, please ask the investigator responsible for explaining the informed consent form to you.

1. Background

Hematopoietic stem cell transplantation (HSCT) is an active and effective intervention method for treating hematopoietic dysfunction, immunodeficiency, and some hematological malignancies. Factors influencing the success of HSCT, besides the collection, cryopreservation, reinfusion of hematopoietic stem cells, and the conditioning regimen, include nutritional status. There are many reasons affecting the nutritional status of patients undergoing HSCT, including: ① The primary disease and its treatment. ② The impact of induction chemotherapy before HSCT or total body irradiation (TBI) on nutritional status. Patients are prone to gastrointestinal symptoms such as anorexia, nausea, vomiting, and diarrhea. High-dose TBI can also easily cause

damage to the gastrointestinal mucosa. Chemotherapy and radiotherapy not only affect appetite, leading to decreased intake, but associated diarrhea also increases the loss of nutrients. ③ Graft-versus-host disease (GVHD) leads to digestive and absorptive dysfunction. Subsequent infections after HSCT may further increase the patient's energy expenditure.

2. Product

The study product is a vanilla-flavored Food for Special Medical Purposes (FSMP) produced by Abbott Laboratories in the United States, which has been approved for marketing by the State Administration for Market Regulation. It is classified as a regular food. Per 100g, it provides 428 kcal of energy, contains 15.9g of protein, 4.3g of dietary fiber, and other nutrients required by the body.

3. Study Objectives

(1). To evaluate the effect of oral FSMP during the peri-transplant period on nutritional indicators in HSCT patients.
(2). To evaluate the effect of oral FSMP during the peri-transplant period on intestinal function in HSCT patients.
(3). To evaluate the effect of oral FSMP during the peri-transplant period on infection, length of stay in the transplant unit, and hospitalization duration.

4. Subjects

Patients with multiple myeloma undergoing hematopoietic stem cell transplantation.

5. Procedures

The study period begins from the preparation phase for hematopoietic stem cell transplantation before entering the transplant unit. Ensure Active (or the specific product name, if '全安素' is a brand name, please verify; currently translated as the product description) will be consumed from the time of entering the transplant unit until 14 days after transplantation, at a dose of 250ml/time, twice a day.

6. Alternative Treatments

This study does not provide alternative treatments. Patients who cannot tolerate oral administration will be excluded.

7. Potential Risks and Discomforts

The study product is a commercially available regular food that complies with Chinese regulations. Participation in this study is not expected to cause health harms. However, there might be mild bloating and diarrhea during the first 1-3 days after consuming

Ensure Active (or the specific product name). Most cases resolve without special treatment.

8. Expected Benefits

By participating in this study, patients can receive Ensure Active (or the specific product name) free of charge and receive nutritional consultation and guidance throughout the process.

9. Free Treatment

The Ensure Active (or the specific product name) oral liquid, body composition measurements, dietary assessments, grip strength measurements, etc., used by the patient will be provided free of charge.

10. Confidentiality

All data related to you in this study (including a copy of the signed informed consent form) will be treated as confidential information. Except for the doctors responsible for this study, any information containing your name will not be provided to anyone under any circumstances. Your identity information will be kept confidential as required by law. Unless required by law, your name, ID number, address, telephone number, or any other personal information will not be disclosed. You will be referred to by a code number in the study. Information linking this code to your identity will be stored in a secure location and accessible only to the investigators.

The Ethics Committee, the medical institution, and clinical monitors may access your medical records in compliance with confidentiality and legal requirements to ensure the accuracy of the collected data.

The results of this study may be used for publication, but personal information will not be disclosed.

11. Re-consent

If the study protocol is amended, re-consent may be required.

12. Subject Responsibilities

Throughout the study period, unless agreed by the investigator and prescribed by a licensed physician, you are not allowed to ingest dietary supplements that may affect the study indicators (such as **protein powder, nutritional powders, Foods for Special Medical Purposes, enteral nutrition preparations, dietary fiber supplements, probiotics, prebiotics, synbiotics**, etc.).

The investigator needs to regularly use and report the usage of the study product according to the study protocol, and you need to cooperate with the investigator to complete the relevant tests.

13. Contact Information

If you have questions related to this study, or if you experience any discomfort or injury during the study, or have questions about participant rights in this study, please contact **[Shen Lijing]**.

If you have any questions or complaints about the research staff during the study, you can contact the Ethics Committee of Renji Hospital, Shanghai Jiao Tong University School of Medicine, at telephone number: **[021-68383364]**.

Informed Consent Form Signature Page

The following section is to be read and completed by the Research Physician

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Subject ID: _____
Investigator's Signature: _____ Date: _____

I confirm that I have explained the details of this clinical trial to the subject. I have provided the subject with a copy of this informed consent form and have answered all his/her questions regarding this study.

The following section is to be read and completed by the Subject

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Subject's Signature: _____ Date: _____
Contact Information: _____

I have received the informed consent form for the aforementioned study, have read it, and understand its contents. I have received sufficient explanation regarding this medical research, including its purpose, risks, my rights, and the research procedures. I had ample opportunity to ask questions before making my decision. I can request more information from the physician responsible for this study at any time.

I understand that my participation in this study is voluntary, and I have the right to change my mind at any time during the study without affecting my future medical care. If I change my mind, I should notify the research physician.

If new information becomes available regarding the study product, I will be informed, as it may affect my decision to continue participating in the study.

I also understand that, as part of this study, access to relevant information in my medical records may be required. Data collected during this study will be reviewed by the medical institution and the sponsor's representatives in accordance with current laws. I know that the data extracted from my medical records will not identify me personally, and all data will be handled with strict confidentiality.

I agree that the data collected during the study may be processed by computer by the sponsor or institutions representing the sponsor.

I confirm that I possess a Chinese Resident Identity Card.

I fully understand that if I participate fully in this study (from the pre-enrollment visit to the end-of-study visit) and comply with all steps and instructions, I will receive up to 200 RMB as transportation subsidy.

I have received a copy of this document and have been informed that the research physician also has another copy of this document. Based on this, I agree to participate in this study.

Subject's Signature: _____ Date: _____
Contact Information: _____