Version 2.0 (1/12/2021)

Jinling Hospital, Nanjing University

CONSENT FORM

TITLE OF STUDY: Effects of oral immunonutritional supplement on 3-year disease-free survival in gastric cancer patients with pathologic stage III after total gastrectomy

PRINCIPAL INVESTIGATOR: Xinying Wang, MD, PhD

We are conducting a clinical trial (a type of research study). Clinical trials include only patients who choose to take part in the study. This consent form will provide information on the procedures and risks involved in the clinical trial. At the same time, this consent form will ask for your permission to use and release the medical information that we will get from you during this study. Please read this informed consent carefully before deciding whether to participate in this study. You can also discuss it with your family and friends. If you have any questions, you can ask the study doctor for more explanation.

This study is being sponsored by Jinling Hospital of Nanjing University. You are being asked to take part in this study because you were admitted to Jinling Hospital with gastric cancer.

WHY IS THIS STUDY BEING DONE?

The nutritional status of patients with gastric cancer (GC) after total gastrectomy continues to deteriorate and lasts a long time after discharge, which is an independent risk factor for mortality. Several studies have found that oral nutritional supplement (ONS) can reduce the incidence of sarcopenia and delay weight loss after total gastrectomy. However, the duration of ONS is usually shorter (6-12 weeks), and the evidence on the efficacy of oral immunonutritional supplement and its effect on long-term disease-free survival (DFS) in patients with GC is limited. Therefore, we conduct a multicenter, randomized study to evaluate the efficacy and safety of oral immunonutritional supplement in treating GC patients with pathologic stage III after total gastrectomy.

It is planned that a total of 696 people will take part in this study from 14 hospitals in Jiangsu province China.

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WHAT WILL HAPPEN IN THE STUDY?

You meet the inclusion criteria for this study, so you will be "randomly" assigned by the computer program to either of the two groups described below. This means that you will have the same probability of being assigned to any group and that you or the doctor will not be able to actively choose the outcome of the assignment.

Group 1: the immunonutrition supplement (INS) group. In the INS group, you will consume two bottles per day of a high-calorie, high-protein ONS [iVital Energy^{TM} (vanilla, 200 mL per bottle, 1.5 kcal per mL), FRESENIUS KABI, Germany] and three capsules of marine fish oil [webber naturals (1.425 g of fish oil per capsule, containing 0.6 g of EPA and 0.3 g of DHA), Canada] per day after discharge for 6 months, in addition to the diet. Group 2: the control (C) group. In the C group, you will receive nutritional counseling and dietary modifications; the intake of protein-rich foods will increase. Before intervention and at the end of intervention, 10ml of your venous blood will be collected to measure the level of ω-3 PUFA in red blood cells. At the same time, you will be followed up for 3 years.

You can stop being a part of this study at any time. If you decide to stop being in the study, please talk to the study doctor first.

WHAT ARE THE RISKS OF THIS STUDY?

The ONS and marine fish oil used in this study are widely used in the nutritional treatment of various diseases. The possible side effects of ONS are typical adverse reactions of enteral nutrition, such as abdominal distension, diarrhea, nausea, vomiting, etc. The possible side effects of fish oil capsules include nausea, belching, nosebleed, and diarrhea. The above side effects are a low incidence and will gradually disappear after drug withdrawal. Furthermore, the combined dose of the EPA and DHA supplement was up to 5 g/day, which did not increase the risk of spontaneous bleeding episodes or bleeding complications. All adverse complications and events attributed to interventions, including unplanned hospitalizations, will be recorded.

There also may be other side effects that we cannot predict. These side effects are often manageable and reversible. If you experience any adverse reactions, talk to the study doctor immediately, and all medically appropriate efforts will be made to prevent

and/or control them by the study doctor.

WHAT ARE THE BENEFITS OF THIS STUDY?

If you agree to take part in this study, you are free to use the iVital Energy™ provided by FRESENIUS KABI (Germany) and marine fish oil provided by WEBBER NATURALS (Canada). Furthermore, you will receive an early nutritional assessment and counseling. And your nutritional status will be regularly monitored.

WHAT ARE THE COSTS?

When you have enrolled in this study, you may receive tests, chemotherapy, and exams, which are standard medical care after surgery. The sponsor will not pay for the routine costs required. However, taking part in this study will not lead to added costs to you or your insurance company. The iVital Energy™ and marine fish oil will be provided free of charge, as is the cost of ω-3 PUFA measurement.

COMPENSATION?

You will receive no payment for taking part in this study.

WHAT ARE YOUR RIGHTS?

Your participation in this study is completely voluntary. You can withdraw from the study at any time without any reason, which will not affect your treatment. All your data and observation records are confidential and for this study only; During the trial, you will have access to relevant information at any time. If you have any problems during the trial or need to consult the relevant questions, you can contact the doctor in charge.

WHAT ABOUT CONFIDENTIAL CONTENT?

The written informed consent stated that the study data would be stored in a computer database and kept confidential under national laws. Patients can only be identified in the database by their initials or patient numbers. The principal investigator is responsible for maintaining the patient identification form or the inclusion form for all patients, including the inclusion code, patient number, full name, and latest address.

STATEMENT OF CONSENT AND AUTHORIZATION

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I have read and fully understood the introduction of "Effects of oral immunonutritional support on long-term prognosis and nutritional status of patients with Stage III gastric Cancer during Chemotherapy after total gastrectomy", and I have been aware of the background, purpose, and research process of this study. The relevant information in this informed consent has also been explained by the study doctor. I agree to participate in this study and to allow the relevant researchers to use my research information for the foregoing purposes. All my questions were satisfactorily answered. When I sign this informed consent, I will not give up any of my rights. As a patient, I am willing to participate in this study and fully cooperate with doctors after understanding the purpose, method, possible benefits, and possible side effects of this study.

Patient Signature: _____

Contact information of Patient: _____

Date of Signature: _____

(If the patient's informed consent capacity is deficient or insufficient, add or replace the following methods)

- Next of Kin
- Parent (patient is a minor)
- Other relationship: _____

Signature of Patient's Legally Authorized Representative: _____

Contact information of Patient's Legally Authorized Representative: _____

Witness to consent process (if applicable): _____

Date of Signature: _____