Study Title: A More Physiological Feeding Process in ICU:the Intermittent Infusion With Semi-solidification of nutrients

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Study Protocol

一. Purpose

1） To investigate whether intermittent feeding with semi-solid nutrients improves the enteral nutrition complications of diarrhea, reflux and aspiration;

2）Observe the feeding intolerance and the efficiency of the EN of critically ill patients;

3）Observe the blood sugar and insulin secretion;

二. Design and method

(1)Single center, randomized, single blind, controlled prospective study;

(2)Inclusion criteria:

1) not less than 14 years old of critical illnesses;
2) No long-term history of oral administration of gastrointestinal motility drugs;
3) Nasogastric tube for enteral nutritional support treatment;
4) No acute pulmonary infection;
5) No previous history of upper gastrointestinal surgery;

(3) exclusion criteria:

1) Refuse into the study;
2) Stay in ICU less than 3 days
3) acute pulmonary infection before entering the ICU;
4)have nutritional contraindications, such as intestinal ischemia or obstruction, gastrointestinal hemorrhage and so on;
5) No enteral nutrition received for less than 3 days;

(4) Abort criteria:

1) Abandoning treatment and discharge, resulting in incomplete data
2) EN contraindications nutrition during treatment;
3) Other condition of researchers think that patients are not fit to continue with the study;

(5)Groups

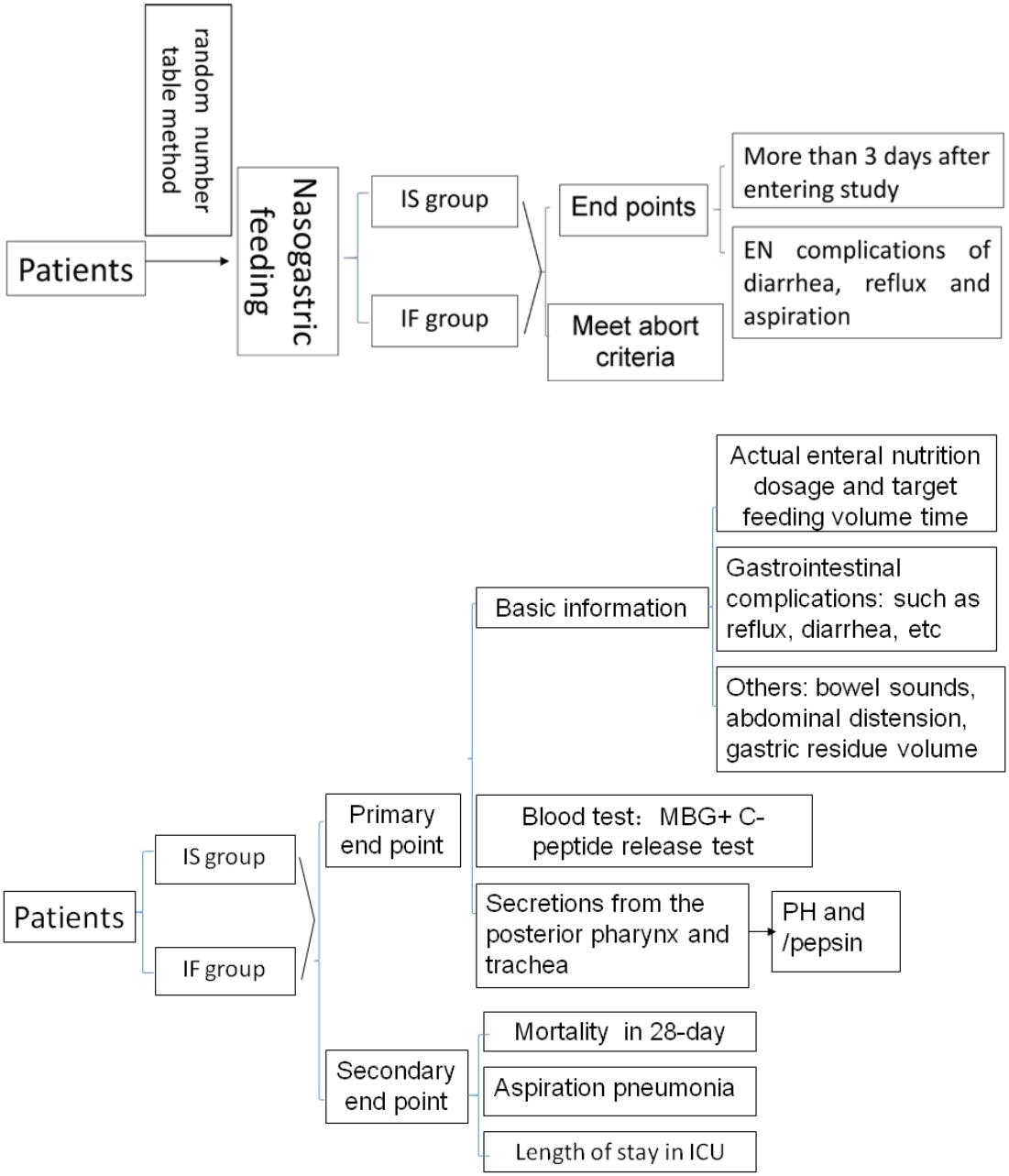
1) intermittent feeding (IF)
2) intermittent feeding with semi-solid nutrients (IS)

If you are assigned to the IS group, you should first receive a package of semi-solid agent to increase the intestinal nutrition viscosity. If you are assigned to the IF group, you will receive the routine nutrition treatment, and the treatment time for both groups is 3 days. After 3 days, you will receive routine enteral nutrition therapy. If there were serious enteral nutrition complications such as aspiration and abdominal distension within 3 days, the experiment would end. The treatment of the two groups only depends on whether semi-solid agent was added, while the rest of the treatment measures were consistent.

(6)Test

Blood (Microvascular blood sugar+ C-peptide release test), Secretions from the posterior pharynx and trachea;

三. Study process



四. How to protect high-risk groups or vulnerable groups

The subject of this study is critically illnesses. Before entering the research group, the researchers must obtain the informed consent by the patient or the agent authorizer about the specific content of the study. For details, please refer to the informed consent.

五. Sample Size Calculating

According to the literature reported, the incidence of gastrointestinal intolerance (FI) is about 30.8%. We presume that δ =-0.05, α =0.025, β =0.20, the non-inferior efficiency test design is adopted and the formula is applied: ($n_1 = n_2 = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 [\pi_1(1-\pi_1) + \pi_2(1-\pi_2)]}{(\pi_1 - \pi_2 - \delta)^2}$) .

六. Data management and confidentiality

Data entry and management were designed in the form of a case report. A case report is a document designed according to the protocol for recording the data of each subject during the

trial.

All records relating to the subject's identity shall be kept confidential and shall not be made public to the extent permitted by applicable laws and/or regulations.

七. Informed consent

The subject of this study is critically illnesses. Before entering the research group, the researchers must obtain the informed consent by the patient or the agent authorizer about the specific content of the study. For details, please refer to the informed consent. The specific procedures for obtaining informed consent include oral and written informed consent from the physician to the patient, patient's family or authorized agent for the above study. The patient volunteered to participate in the study. Patients understand that they can withdraw from the study at any time for no reason, without affecting their future treatment. At the same time, the patient or the agent authorizer will obtain a copy of this informed consent. At the same time, the subjects included in this study were critically illnesses, and the subjects, told and signed, were mainly immediate family members.

八. Report of adverse events

After entering this study, there were some possible adverse reactions:

(1) Diarrhea, which is most popular, may cause water and electrolyte disturbance in severe cases;

(2) Nausea and vomiting, and stomach retention;

(3) High and low blood sugar;

(4) Aspiration is one of the more serious complications. Patients with weakness, old age or coma are more likely to have liquid diet reflux, especially those with esophageal reflux.

(5)Take off and plug the pipe.

Patients will not receive additional treatment or take additional risks for participating in the study