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

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AF42 THE informed consent form of Second Affiliated Hospital, Zhejiang University school of Medicine

Respected patient:

We invite you to participate in a clinical study of "a new type of enteral feeding in critical illness: intermittent semi-solid feeding", before you participated, please read the following carefully, which can help you understand the study and why we conducted, the procedure and duration, the benefits, risks, and inconvenience of this study. The following is the introduction of this study:

一. Background and purpose：

Enteral nutrition therapy is an important part of the treatment of critical illness. Currently, there are two feeding types in ICU: continuous feeding or intermittent feeding. Continuous feeding is thought to be better tolerated by patients with limited absorptive gut surface area or gastrointestinal dysfunction, but is associated with more tube clogging. It also requires the subject to be attached to an infusion pump for significant periods of time. Intermittent infusion mimics a more physiologic feeding process that allows greater subject mobility.Studies had found that about 79% patients with gastrointestinal nutrition presented with nutritional interruptions, that the clinical operation or examination was the main reason (45.1%), followed by high residual amount in the stomach, diarrhea, stomach tube, such as nasogastric tube shift and vomiting. In theory, intermittent feeding can effectively reduce the feeding interrupt, promotes gastrointestinal nutrition absorption, which have a certain correlation with the incidence of complications and mortality in critically illness. However, the rate of diarrhea and aspiration may be higher than that of continuous feeding due to the fast infusion rate of conventional intermittent feeding. Aspiration and aspiration pneumonia were serious life-threatening complications of enteral nutrition application. According to different studies, the incidence fluctuated between 4% and 70%, and the complications of gastrointestinal tract, which are commonly reflux (20%), diarrhea (63%) and constipation (5-83%), all seriously affect patients access to adequate enteral nutrition, and reflux was also a high risk factor for aspiration and aspiration pneumonia.

Therefore, we design this study, mainly including the following purposes:

1) 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. Procedures：

If you need enteral nutrition treatment, you will be evaluated for inclusion. After being selected, you will be randomly assigned to either intermittent feeding (IF) or intermittent feeding with semi-solid nutrients (IS), that is, you will have equal opportunities to both group. 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. The team will be in the follow-up for 28 days respectively. The content of follow-up on the 28th day was the patient prognosis.

三. What do you need to do if you participate in the study

You will be randomly assigned to either intermittent feeding (IF) or intermittent feeding with semi-solid nutrients (IS). The treatment plan can be seen in the part of procedure. In addition, you need to cooperate with a small amount of blood collection at regular intervals. Blood glucose was routinely monitored by Q2-4h. External specimens (postpharyngeal secretions and/or intratracheal secretions) will be provided and the expense was free during enrollment. You will not be required to participate in this study for additional testing and examination items.

四. Benefit from participating in this study

(1) provide sufficient intestinal nutrition,and reduce the incidence of diarrhea, reflux, aspiration or aspiration pneumonia.

(2) may reduce mortality of 28 days and improve the long-term prognosis;

(3) the incidence of nosocomial pneumonia and diarrhoea rates decline, to a certain extent, reduce hospitalization expenses;

(4) treatment of early out of bed and physical activity, to be effective in preventing deep vein thrombosis, may help reduce length of stay in ICU.

This is a study of the food additive, the product itself does not exist a similar drug side effects, and enteral nutrition was a routine treatments, semi-solid agent is already available in Japan and other countries, no obvious side effects in the process of application.

五. Possible adverse reactions、risks and measures of the risk prevention

If you take part in this study, you will be placed nasogastric tube, including some possible complications:

1) when placed: including nasal local mucosal bleeding, nausea, vomiting, tears, choking cough, strayed into the trachea, serious cause arytenoid dislocation;

2) obstructive jaundice, nasal septum abscess and esophageal erosion bleeding, or nasal bleeding;

3) stomach bleeding, etc in tube drawing.

Placing nasogastric tube is a routine treatment in ICU, you will not receive additional treatment by in the study. In order to prevent the risk of nasogastric tube placement to the minimum, firstly, we will communicate with the patient and family members about the risk before placement. Secondly, we need to assess whether the patient has a contraindication of nasogastric tube, such as skull base fracture before placement. Thirdly, experienced clinicians should be selected for placement. Meanwhile, in the process of indwelling, nurses and physicians should be instructed to pay attention to the complications and timely deal with the symptoms.

you may have the following adverse reactions in the process of EN:

(1) gastrointestinal complications: nausea, vomiting, diarrhea, abdominal distension and constipation, severe cases may induce acute intestinal obstruction;
(2) Metabolic complications: water electrolyte disorder and abnormal transaminase, non ketosis high sugar, high permeability coma;
(3) Tube feeding syndrome: low phosphorus concentration;
(4) Complications of infection: aspiration pneumonia;
(5) Mechanical complications: nasogastric tube related complications, such as tube blocking;
(6) Mental impact: all kinds of discomfort, hunger, restrictions, and pessimistic.

You may have or not some of the above adverse reactions, but these adverse reactions are usually rare and can be gradually relieved after stopping enteral nutrition. If necessary, the adverse will be treated accordingly. All the above operations and enteral nutrition are routine operation in ICU. During the period of clinical research, we will pay close attention to related complications of enteral nutrition. Patients at risk for obvious or gastrointestinal dysfunction were usually applied in promote gastric dynamic medicine to promote gastric emptying, kept patients with the head of a bed up 30 to 45 °, etc. You will not add additional testing and inspection items to this study.

六. Cost information

There is no need to pay the cost of semi-solid agent, and the study will not increase your additional examination or examination when compared with the clinical routine, that is, there will be no additional expense or fee reduction.

七. Compensation for participation in the study

Placing nasogastric tube and enteral nutrition were routine treatment in ICU, and the experiment for the study of the food, the product is already available in Japan and other countries, mainly study in the healthy people and elderly people, better security, if the study period of complications and clear as semi-solid agent, the late related medical expenses have provided research funding, but you will not receive additional economic compensation for taking part in the research.

八. Alternative solution

If you do not want to participate in this study, you can also use other treatment options, such as nasoenteral nutrition, the researcher will introduce other treatment options.

九. Confidentiality of personal information

Your medical records (including study records and physical and chemical examination reports, etc.) will be kept in the hospital as required. Your medical records will not be accessible to any person who has nothing to do with the study, except for the investigator, the ethics committee, the supervisor, the audit and the pharmaceutical administration. A public report of the results of this study will not disclose your personal identity. We will do all that we can to protect the privacy of your medical information.

十. Termination of participation

Participation in this study depends entirely on your willingness. You may refuse to participate in this study or withdraw from the study for no reason at any time during the study process, which will not affect your relationship with the doctor, will not affect the loss of your medical or other benefits. In addition, for the following reasons, may terminate your participation in this study:

1） you do not follow the doctor's advice.

2） You may need to have taken place in treatment of severe cases.

3） The doctor thought, termination of study best for your health and well-being.

十一. Ethics Committee

This study has been reported to the human research ethics committee of Second Affiliated Hospital, Zhejiang University School of Medicine, and it has been reviewed comprehensively by the committee included the risk assessment of the subjects, and has been approved. For matters related to ethics and rights, please contact the human research ethics committee of Second Affiliated Hospital, Zhejiang University School of Medicine,, tel: 0571-87783759;Evening (total duty):13757118366; Email address: HREC2013@126.com

we confirm that I have read and understood the informed consent for this study, voluntarily accept the treatment in this study, and agree to use my medical data for the publication of this study.

Subject signature:_____contact information: _____ date:_____

Signature of agent:_____Relationship with subjects:_____ contact information: ___ date:_____

Witness:_____ contact information: _____ date:_____

I confirm that I have explained to the patient the details of the study, including its rights and possible benefits and risks, and given a copy of the signed informed consent.

Investigator's signature:_____ contact information: _____ date:_____