# Nutritional support algorithm for critically ill patients

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
20/04/2016		[X] Protocol		
Registration date 26/05/2016	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		[X] Individual participant data		
14/06/2023	Nutritional, Metabolic, Endocrine			

#### Plain English summary of protocol

Background and study aims

Nutritional support is of vital importance for patients being treated in the intensive care unit (ICU) patients. These critically ill patients are at risk of not having adequate nutrition. Clinicians, for example, may delay enteral nutrition support due to the nature of the critical illness or after a patient has undergone major surgery. However, there is evidence that giving enteral nutrition early (that is, nutrition administered directly to the digestive system, for example into the stomach though a feeding tube) on is beneficial for a variety of reasons, such as reduced risk of developing ventilator associated pneumonia, protecting the enteral mucus (lining of the digestive system) and even a reduced risk of death while in hospital. However, it is not known at present how enteral nutrition support using a structured algorithm would benefit the critically ill. The study is designed to investigate this and provide evidence for using such a structured algorithm.

#### Who can participate?

Critically ill patients expected to stay in ICU for more than 3 days.

#### What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are provided enteral nutrition support via the structured algorithm. Those in group 2 (control) are not provided enteral nutrition support via the structured algorithm. All participants are followed up for the next 28 days, or until death, assessing them to see whether they develop ventilator associated pneumonia, for example, how long they require mechanical ventilation and the amount of nutrition they receive.

What are the possible benefits and risks of participating?

Participants in the intervention group may be more likely to receive adequate enteral nutrition earlier than they may otherwise have done.

Where is the study run from? A total of ten hospitals in Zhejiang, China When is the study starting and how long is it expected to run for? April 2016 to December 2016

Who is funding the study?
Zhejiang Provincial People's Hospital (China)

Who is the main contact?

1. Dr Renhua Sun (scientific)
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### Contact information

#### Type(s)

Scientific

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### Additional identifiers

EudraCT/CTIS number

**IRAS** number

 ${\bf Clinical Trials. gov\ number}$ 

### Secondary identifying numbers

N/A

### Study information

#### Scientific Title

Effectiveness of nutritional support algorithm on outcomes for critically ill patients

#### **Study objectives**

We hypothesized that the use of a enteral nutritional support algorithm would improve clinical outcomes for critically ill patients

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics committee of Zhejiang Provincial People's Hospital, 27/04/2016, ref: 2016JS001

#### Study design

Interventional non-randomised study

#### Primary study design

Interventional

#### Secondary study design

Non randomised study

#### Study setting(s)

Hospital

### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied

**Enteral feeding** 

#### **Interventions**

This study is evaluating an enteral nutritional support algorithm.

Critically ill patients are randomly allocated to one of two groups:

- 1. Those fed though the enteral nutritional support algorithm (intervention)
- 2. Those for which there is no protocol for enteral feeding (control)

The nutritional support algorithm is as follows:

- 1. Enteral feeding is considered when the subject is hemodynamically stable and fulfills the criteria
- 1.1. Mean arterial blood pressure > 65 mmHg
- 1.2. Serum lactate <4 mmil/l; and norepinephrine infusion rate <12.5 mcg/min
- 2. Then the gastrointestinal function is assessed and categorized as follows:
- 2.1. Normal function
- 2.2. Acute gastrointestinal injury grade 1-3
- 2.3. Contraindications for enteral feeding such as ischemic bowel disease, perforation, obstruction and AGI grade 3

Enteral feeding of 25 ml/hr is started for participants in category 2.1. Enteral feeding at rate of 10-15 ml/hr is started for participants in category 2.2. Total parenteral nutrition support is started for participants in category 2.3.

Patients are followed for 28 days after randomization or until death, depending on which occurs first. They are not followed up after conclusion of the study.

#### Intervention Type

Other

#### Primary outcome measure

28-day mortality

#### Secondary outcome measures

- 1. Incidence of ventilator associated pneumonia
- 2. Length of stay in ICU and hospital
- 3. Duration of mechanical ventilation
- 4. Biomarkers of nutritional status, including albumin, pre-albumin, chemistry profile, CD3, CD8, IgA, IgG, HLA-DR. They are measured via blood samples taken on a daily basis after enrollment into the study
- 5. Total amount of nutrition and the proportions of enteral and parenteral nutrition, measured by summing up calories intakes for the whole study period. Calories include enteral nutrition (commercial formula with fixed calorie per unit volume), and parenteral nutrition

### Overall study start date

03/05/2016

### Completion date

18/12/2016

### Eligibility

#### Key inclusion criteria

Critically ill patients expected to stay in ICU for more than 3 days

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

Both

#### Target number of participants

350

#### Key exclusion criteria

- 1. Previous EN within 7 days of current episode of ICU admission
- 2. Burn patients
- 3. Pregnancy and breast feeding
- 4. Patients with PEJ, PEG

#### Date of first enrolment

05/05/2016

#### Date of final enrolment

18/12/2016

### Locations

#### Countries of recruitment

China

# Study participating centre Zhejiang Provincial People's Hospital

Zhejiang China

310000

### Study participating centre Zhejiang Provincial TCM Hospital

China 310000

#### Study participating centre Huzhou Central Hospital

198 Hongqi Rd Wuxing Huzhou Zhejiang China

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### Study participating centre Shaoxing People's Hospital

No.568, Zhongxing North Road Shaoxing Zhejiang China

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### Study participating centre YiWu Central Hospital

No.699, Jiangdong Road Yiwu Zhejiang China

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### Study participating centre NingBo First Hospital

No.59, LiuTing Street NingBo Zhejiang China

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# Study participating centre TaiZhou Hospital

No.150, Ximen Street Taizhou Zhejiang China

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#### Study participating centre QuZhou People's Hospital

2 Zhouloudi Quzhou 324000 Zhejiang China

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### Study participating centre LiShui People's Hospital

NO.15, LiShui City Zhejiang China

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# Study participating centre Jinhua Municipal Central Hospital

351#, Mingyue Street Jinhua Zhejiang China

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### Sponsor information

#### Organisation

Zhejiang Provincial People's Hospital

#### Sponsor details

158#, Shangtang Road Hangzhou China 310014

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/03k14e164

### Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Zhejiang Provincial People's Hospital

### **Results and Publications**

### Publication and dissemination plan

Intention to publish date 18/12/2016

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/08/2016		Yes	No
Results article	results	03/08/2017		Yes	No
<u>Dataset</u>			14/06/2023	No	No