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Nutritional support algorithm for critically ill patients

Submission date
20/04/2016

Recruitment status
No longer recruiting

Registration date
26/05/2016

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

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)
zjpphicu@126.com
2. Dr Zhongheng Zhang (scientific)
zh_zhang1984@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Renhua Sun

Contact details
158#, Shangtang Road
Hangzhou
China
310014
+86 (0)571 85893281
zjpphicu@126.com

Type(s)
Scientific

Contact name
Dr Zhongheng Zhang

Contact details
351#, Mingyue Street
Jinhua, Zhejiang,
China
321000
+86 (0)579 82553393
zh_zhang1984@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.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
-

Study participating centre
YiWu Central Hospital
No.699,Jiangdong Road
Yiwu
Zhejiang
China
-

Study participating centre
NingBo First Hospital
No.59, LiuTing Street
NingBo
Zhejiang
China
-

Study participating centre
TaiZhou Hospital
No.150, Ximen Street
Taizhou
Zhejiang
China
-

Study participating centre
QuZhou People's Hospital
2 Zhouloudi
Quzhou 324000
Zhejiang
China
-

Study participating centre
LiShui People's Hospital
NO.15, LiShui City
Zhejiang
China
-

Study participating centre
Jinhua Municipal Central Hospital
351#, Mingyue Street
Jinhua
Zhejiang
China
-

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
Dataset			14/06/2023	No	No