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Bedside nose-to-intestine feeding with easily digested liquid nutrition for adults with acute respiratory distress and bleeding in the upper stomach or gut

Submission date
22/08/2025

Recruitment status
No longer recruiting

Registration date
22/08/2025

Overall study status
Completed

Last Edited
22/08/2025

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People in intensive care with severe breathing problems (acute respiratory distress) who have recently had bleeding in the upper stomach or gut often struggle to meet their nutritional needs. This study observes usual care at two hospitals to learn whether feeding into the small intestine using an easily digested short-peptide liquid is associated with better 7-day nutritional recovery and safe, practical care compared with conventional care without this small-intestine tube.

Who can participate?
Patients aged 18 years or older in intensive care with moderate–to–severe acute respiratory distress and recent upper gut bleeding that has been stable for at least 48 hours, who need tube feeding because they cannot take food by mouth.

What does the study involve?
Doctors and nurses provide routine care as usual. Some patients receive feeding through a soft tube placed from the nose into the small intestine with a short-peptide formula; others receive conventional care without this tube. The study team collects information already recorded in medical notes, including daily calories and protein during the first week, blood tests related to nutrition and inflammation on Days 1, 4, and 7, and any feeding intolerance or complications. Patients are followed in intensive care until discharge, up to 28 days.

What are the possible benefits and risks of participating?
There is no guaranteed direct benefit. The information may help improve nutrition care for future patients. There are no extra risks from observation alone. If any additional blood sample is requested beyond routine care, the risk is the same as a standard blood draw (temporary discomfort or bruising).

Where is the study run from?
Xiamen Chang Gung Hospital, Xiamen, China, and Chang Gung Memorial Hospital – Linkou Branch, Taoyuan, (Taiwan)

When is the study starting and how long is it expected to run for?
May 2019 to April 2024

Who is funding the study?
1. Key Special Projects of the Xiamen Science and Technology Bureau (project number 3502Z20214ZD1114)
2. Chang Gung Memorial Hospital Research Project (CMRPG1E0874)

Who is the main contact?
Xu Dongping, xdp0592@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
3502Z20214ZD1114, CMRPG1E0874

Study information

Scientific Title
Bedside nasojejunal short-peptide feeding vs standard care for adults with acute respiratory distress syndrome and upper gastrointestinal bleeding: a two-centre prospective cohort study

Acronym

SPEAR-NJ

Study objectives
The objective is to evaluate, in a two-centre, two-arm prospective observational cohort, whether early short-peptide enteral nutrition delivered via bedside nasojejunal tube is associated with improved 7-day nutritional recovery in intensive-care adults with acute respiratory distress syndrome and recent upper gastrointestinal bleeding, compared with conventional care without nasojejunal feeding (including whole-protein nasogastric or delayed enteral nutrition). The primary question is the between-group difference in change in serum prealbumin from baseline to Day 7. Secondary questions are the between-group differences in serum albumin, delivered energy/protein to Day 7, rates of feeding intolerance, aspiration and rebleeding, procedure-related complications, and intensive-care length of stay.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/05/2019, Xiamen Chang Gung Hospital Medical Ethics Committee (12F, Inpatient Building, No. 123 Xiafei Road, Haicang District, Xiamen, 361028, China; +86 (0)592 620 2834; cln0212@adm.cgmh.com.cn), ref: AF-IRB-007-01.0

Study design
Multicentre (two-centre) prospective longitudinal observational cohort study

Primary study design
Observational

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Acute respiratory distress syndrome complicated by recent upper gastrointestinal bleeding in adult intensive-care patients

Interventions
This two-centre prospective observational cohort enrolls adults in intensive care with acute respiratory distress syndrome and recent upper gastrointestinal bleeding. Exposure groups are defined by routine clinical practice: (i) bedside nasojejunal short-peptide enteral feeding and (ii) conventional care without nasojejunal feeding (which may include whole-protein nasogastric or delayed enteral nutrition). Treatments are chosen by the attending team; investigators do not randomise or assign care. When nasojejunal feeding is used, placement is performed at the bedside per local protocol with radiographic confirmation, then continuous pump feeding of a short-peptide formula. The study collects baseline demographics and severity scores, daily delivered energy/protein on Days 1–7, serum prealbumin and albumin at baseline and Day 7, and monitors feeding intolerance, aspiration, rebleeding, and procedure-related complications through Day 7. Clinical outcomes (e.g., ventilator days and intensive-care length of stay) are followed to ICU discharge, capped at 28 days. Masking is not applicable.

Intervention Type
Mixed

Primary outcome(s)
Serum prealbumin (mg/L) measured using routine hospital biochemistry on Day 1 and Day 7; endpoint is the change from Day 1 to Day 7

Key secondary outcome(s))
1. Serum albumin (g/L) and total protein (g/dL) measured by routine biochemistry on Days 1 and 7; change Day 17
2. C-reactive protein (mg/L) and interleukin-6 (pg/mL) measured by hospital laboratory on Days 1, 4, and 7; change Day 17
3. Lymphocyte count (×10^9/L) from complete blood count (CBC) on Days 1 and 7; change Day 17
4. Nitrogen balance (g/day) calculated from urinary urea nitrogen on Days 1 and 7; change Day 17
5. Delivered energy (kcal/kg/day) and protein (g/kg/day) abstracted from ICU nutrition charts daily on Days 1–7; endpoints are mean intake over Days 1–7 and cumulative intake by Day 7
6. Feeding intolerance events (e.g., GRV >500 ml, vomiting, diarrhea, abdominal distension) recorded via standardized checklist every 6 hours through Day 7; endpoint is any event by Day 7 and total events Days 1–7
7. ICU-acquired infections (ventilator-associated pneumonia, bloodstream infection, CLABSI) diagnosed per site protocols to ICU discharge or Day 28; endpoint is any occurrence and time to first event
8. Ventilator-free days (VFDs) to Day 14; endpoint is days alive and free from invasive ventilation between Day 0 and Day 14 (and proportion achieving ≥14 VFDs)
9. ICU length of stay (days) from enrolment to ICU discharge (capped at Day 28)
10. 28-day all-cause mortality

Completion date
28/04/2024

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Moderate–to–severe acute respiratory distress syndrome per the Berlin Definition (PaO_2/FiO_2 ≤200 mmHg on PEEP ≥5 cm H_2O)
3. Upper gastrointestinal bleeding resolved for ≥48 hours: no active hematemesis or melena, hemodynamic stability (MAP ≥65 mmHg without vasopressor escalation), and stable hemoglobin (≤1.5 g/dL drop over 24 h without transfusion)
4. Requires enteral nutrition and cannot take orally due to sedation, endotracheal intubation, or dysphagia
5. Anticipated ICU stay ≥72 hours from enrolment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
100 years

Sex
All

Total final enrolment
472

Key exclusion criteria
1. Ongoing or recurrent gastrointestinal bleeding at screening (new melena, hematemesis, or hemodynamic decompensation requiring transfusion)
2. Allergy or intolerance to short-peptide enteral nutrition components (whey protein hydrolysate, MCT oil)
3. History of major gastrointestinal surgery (e.g., gastrectomy, small-bowel resection) or known mechanical obstruction
4. Glasgow Coma Scale <6 not attributable to sedation (confirmed by RASS scores and medication review)
5. Advanced hepatic encephalopathy (West Haven grade III–IV)
6. Palliative status or a documented plan to withdraw life-sustaining therapy within 48 hours

Date of first enrolment
01/03/2023

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
China

Study participating centre
Xiamen Chang Gung Hospital
No. 123 Xiafei Road
Haicang District
Xiamen
China
361028

Study participating centre
Chang Gung Memorial Hospital – Linkou Branch (Medical Critical Care Unit)
No. 5, Fuxing Street
Guishan District
Taoyuan

Taiwan
33305

Sponsor information

Organisation
Xiamen Science and Technology Bureau Health Guidance Project Research Project

Funder(s)

Funder type
Research organisation

Funder Name
Xiamen Science and Technology Bureau Health Guidance Project Research Project

Funder Name
Chang Gung Memorial Hospital Research Project

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the corresponding author, Xu Dongping (xdp0592@163.com). De-identified individual participant data will include baseline demographics and severity scores, daily energy /protein delivery (Days 1–7), laboratory biomarkers (prealbumin, albumin, C-reactive protein, interleukin-6, lymphocyte count) at prespecified time points, adverse events, clinical outcomes to intensive-care discharge (capped at 28 days), and a site code. Data will be released starting 6 months after primary results are published and remain available for 5 years. Access will be granted to researchers with methodologically sound proposals for non-commercial, ethically approved analyses; requests must include an analysis plan and evidence of local IRB/ethics approval and will require a signed data use agreement. Anonymisation will remove direct identifiers, offset dates, and suppress rare combinations to minimise re-identification risk. Sharing is subject to approval by the hospital ethics committees and to applicable privacy laws; where consent limits broader sharing, only aggregate data will be provided. The final protocol and analysis code will be shared alongside the publication or via a public repository, with instructions for requesting IPD included.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			22/08/2025	No	No
Other files			22/08/2025	No	No
Participant information sheet			22/08/2025	No	Yes
Protocol file			22/08/2025	No	No
Statistical Analysis Plan			22/08/2025	No	No