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Using gentle sinus drainage to stop food or liquid going into the lungs in ICU patients with swallowing problems

Submission date 27/11/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/12/2025	**Overall study status** Completed	
Last Edited 19/12/2025	**Condition category** Infections and Infestations	

Plain English summary of protocol
Plain English summary of protocol not provided at registration

Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title
Continuous low-pressure pyriform sinus drainage to prevent silent aspiration in ICU-acquired dysphagia: a randomized clinical trial

Study objectives
To determine whether continuous low negative-pressure pyriform sinus drainage reduces silent aspiration incidence and improves clinical outcomes in ICU-ASD patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/03/2023, Ethics Committee of Fujian Provincial Hospital Affiliated to Fuzhou University (No. 134, Dongjie Street, Fuzhou City, Fujian Province, , 350000, China; +86 15960166892; 532019705@qq.com), ref: K2023-02-014

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied

Continuous low-pressure pyriform recess drainage to prevent occult aspiration in ICU-acquired dysphagia patients

Interventions

Eligible ICU patients (adults) were screened after ≥48 hours of invasive mechanical ventilation and following extubation/decannulation. Dysphagia was confirmed within 24 hours using the Gugging Swallowing Screen (GUSS). After written informed consent, participants were randomised 1:1 to control or intervention. Baseline clinical data and baseline laboratory tests were recorded. Participants then received the allocated care from enrolment until swallowing recovery or ICU discharge. Swallowing assessments were performed regularly until recovery or censored at ICU discharge or day 28 (whichever occurred first). Survival status was followed to day 90 (telephone follow-up and/or hospital records).

Control group (standard care / aspiration precaution bundle):
Participants received a multidisciplinary aspiration-precaution bundle, including (as clinically appropriate): head-of-bed elevation; positioning/postural adjustments; early mobilisation; swallowing rehabilitation exercises; airway secretion management and suctioning when needed; cautious feeding/texture modification and feeding intolerance management; and oral care.

Intervention group (standard care + pyriform sinus suction drainage):
In addition to the same standard care bundle, participants received continuous low-pressure suction drainage of one pyriform sinus (typically the right side unless anatomy dictated otherwise). Under fibreoptic visualisation (laryngoscope/bronchoscope), a soft suction catheter (approx. 10 Fr) was inserted transnasally and positioned with the tip in the pyriform fossa; correct placement was confirmed endoscopically. The catheter was secured, connected to continuous low vacuum suction, and checked each nursing shift for position/patency. Suction was discontinued when swallowing recovered, the participant was discharged/transferred out of ICU, or if clinically indicated due to intolerance/complication. The catheter was not routinely changed unless displaced or blocked.

Duration of observation/follow-up:
Intervention exposure (catheter in situ): from enrolment until swallowing recovery or ICU discharge (typical duration around several days; median about 5 days).

Clinical observation for swallowing outcomes: from randomisation until recovery, ICU discharge, or day 28 (censored).
Mortality follow-up: day 28 and day 90 after enrolment (via hospital records and post-discharge contact).

Randomisation method:
A computer-generated random sequence (permuted blocks) was used with allocation concealment via sequentially numbered, sealed opaque envelopes prepared by a team member not involved in clinical care.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Swallowing function recovery time measured using data collected from medical records on the number of days from randomization to the first day the patient achieved full oral intake of regular solids and thin liquids without signs of aspiration, maintained SaO_2 >90% on room air

during swallowing, and had a normal swallow exam by the speech therapist (Gugging Swallowing Screen [GUSS] score = 20) at a daily assessment by ICU nurses and formal evaluation every 2–3 days by a trained speech-language pathologist until recovery or censored (ICU discharge or day 28)

2. ICU length of stay (LOS) measured using data collected from medical records on the number of days from ICU admission to ICU discharge (or death in ICU if applicable) at one time point

Key secondary outcome(s))
1. Incidence of silent aspiration, in the absence of overt clinical signs of aspiration (no coughing, choking, wet voice, or desaturation during the event) measured using the detection of pepsin (>25 ng/mL by quantitative ELISA, PepTest®) in tracheal aspirates (intubated patients) or oropharyngeal/tracheal secretions (extubated or tracheostomized patients) at study days 1, 3, 5, and 7

2. Incidence of aspiration pneumonia measured using data collected from medical records on new lung infiltrate on chest X-ray plus ≥2 of the following: fever >38°C or WBC >12×10⁹/L, purulent sputum, positive respiratory culture; and evidence of aspiration risk (witnessed aspiration event or positive pepsin assay in respiratory secretions); all cases were adjudicated by two independent ICU physicians blinded to allocation at one time point

3. 28-day and 90-day all-cause mortality measured using data collected from medical records on all-cause mortality recorded at day 28 and day 90 after ICU admission, confirmed via hospital records and post-discharge telephone follow-up at at one time point

4. Inflammatory markers: Serum C-reactive protein (CRP, mg/L) and white blood cell count (WBC, ×10⁹/L) measured using standard hospital laboratory methods (routine venous blood sampling; CRP assay performed in the central laboratory; automated hematology analyser) at ICU day 5 (±1 day) (with baseline values recorded at enrolment/ICU admission as per routine clinical practice)

5. Swallowing-related outcomes measured using the Gugging Swallowing Screen (GUSS) score (0–20) at daily until recovery time to resumption of any oral feeding (days from randomization to first successful oral intake of any consistency), or need for re-intubation for airway protection

Completion date
01/03/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. ICU admission with invasive mechanical ventilation for ≥ 48 hours and extubation
3. Conscious patients assessed as having ICU-ASD by GUSS within 24 hours of extubation
4. Tracheostomy patients who have recovered stable consciousness and are able to complete functional assessments
5. Agree to participate in this study and sign informed consent form

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
111

Key exclusion criteria
1. Impaired consciousness preventing completion of swallowing assessment
2. Severe cognitive impairment or mental illness
3. Comorbid severe oropharyngeal bleeding tendency or coagulation dysfunction
4. Pre-existing aspiration or aspiration pneumonia
5. Comorbid gastroesophageal reflux or tracheoesophageal fistula, or other diseases that may affect the study results

Date of first enrolment
01/02/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
China

Sponsor information

Organisation
Fujian Provincial Hospital

ROR
https://ror.org/045wzwx52

Organisation
Fujian Medical University

ROR
https://ror.org/050s6ns64

Funder(s)

Funder type

Funder Name
Fujian Provincial Hospital

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			15/12/2025	No	No
Statistical Analysis Plan			15/12/2025	No	No