STUDY PROTOCOL

Continuous Low-Pressure Pyriform Sinus Suction Drainage to Prevent Silent Aspiration in ICU-Acquired Dysphagia: A Single-Center Randomized Controlled Trial

Yun Li,Department of Critical Care Medicine, Provincial Affiliated Hospital of Fuzhou University, China

Administrative information

Item	Details
Study title (scientific)	Continuous Low-Pressure Pyriform Sinus Suction Drainage to Prevent Silent Aspiration in ICU-Acquired Dysphagia: A Single-Center Randomized Controlled Trial
Public title	Continuous low-pressure pyriform sinus drainage to prevent silent aspiration in ICU-acquired dysphagia (ICU-AD)
Trial design	Single-center, prospective, parallel-group, superiority randomized controlled trial (1:1 allocation)
Study setting	Adult intensive care unit (ICU), single tertiary hospital in China (single center)
Sponsor	Provincial Affiliated Hospital of Fuzhou University
Coordinating center	Department of Critical Care Medicine
Principal investigator	Yun Li
Steering committee	Fayang Lian , approval staff of the hospital's ethics center
Data monitoring committee (DMC)	Not planned (low-risk device-like intervention; single-center). Safety monitored by investigators.
Protocol version/date	15 Dec 2025
Funding	No
Conflicts of interest	No
Ethics approval	Approved by the hospital ethics committee (approval number: K2023-02-14). Informed consent obtained from participants or surrogates.

Background and rationale

ICU-acquired dysphagia (ICU-AD) is a common complication after prolonged critical illness and mechanical ventilation. Dysphagia increases the risk of aspiration (including silent aspiration), aspiration pneumonia, prolonged ICU stay, and mortality. Current prevention strategies are largely behavioural or supportive and may not directly remove pooled secretions that can be silently aspirated. We hypothesize that continuous low-pressure suction of the pyriform sinus can proactively remove accumulated secretions and reduce silent aspiration, thereby improving swallowing recovery and downstream clinical outcomes.

Objectives

Primary objective:

To determine whether adding continuous low-pressure pyriform sinus suction drainage to standard dysphagia care reduces silent aspiration and accelerates swallowing recovery in ICU patients with ICU-AD.

Secondary objectives:

• To assess whether the intervention reduces aspiration pneumonia.

• To evaluate impacts on ICU length of stay and short- and medium-term mortality (28-day and 90-day).

• To evaluate systemic inflammation markers (CRP and WBC) at ICU day 5 (±1 day).

• To assess safety and tolerability of the suction drainage intervention.

Trial design

This is a single-center, prospective, parallel-group, two-arm superiority RCT with 1:1 allocation to intervention versus control. Due to the nature of the intervention, participant and treating staff blinding is not feasible; outcome assessment will be standardized and based on predefined criteria.

Methods: participants, interventions and outcomes

Study setting

Adult ICU of a tertiary hospital in China. Recruitment period in the completed study was February 2024 to December 2024.

Eligibility criteria

Inclusion criteria:

• Adult ICU patients (≥18 years).

• Received invasive mechanical ventilation for ≥48 hours.

• Successfully extubated (endotracheal tube removal) or decannulated.

• Screen-positive for dysphagia and confirmed ICU-acquired dysphagia using the Gugging Swallowing Screen (GUSS) within 24 hours of eligibility assessment.

• Informed consent obtained from patient or legally authorized representative.

Exclusion criteria (key examples; final list aligned with study record):

• Pre-existing dysphagia prior to ICU admission or structural diseases affecting swallowing.

• Neurological disorders severely affecting swallowing function unrelated to the ICU course (e.g., progressive neurodegenerative disease) [specify as per final dataset].

• Active significant oropharyngeal or gastrointestinal bleeding.

• Contraindication to nasal catheter placement (e.g., severe nasal trauma, base of skull fracture).

• Expected death or withdrawal of care within 24–48 hours, or participation in another interventional trial judged to interfere.

Interventions (TIDieR description)

Control: Standard dysphagia care / aspiration prevention bundle

All participants receive comprehensive standard dysphagia care and aspiration prevention measures delivered by trained ICU nurses and rehabilitation staff. Core components include: head-of-bed elevation 30°–45° unless contraindicated; positioning/postural adjustments; early mobilisation; swallowing rehabilitation exercises; secretion management and suctioning as needed; cautious feeding/texture modification; prokinetic use and gastric residual checks as clinically indicated; standard oral hygiene; and daily clinical review.

Intervention: Standard care plus continuous low-pressure pyriform sinus suction drainage

Intervention name: Continuous low-pressure pyriform sinus suction drainage (unilateral).

Rationale: remove pooled pharyngeal secretions to reduce silent aspiration risk.

Materials:

• Soft suction catheter approximately 10 Fr (size may be adjusted by anatomy).

• Fibreoptic visualisation (laryngoscope/bronchoscope) for placement confirmation.

• Continuous suction device with adjustable low negative pressure.

Procedures:

• After randomisation, under fibreoptic visualisation, insert the catheter transnasally and position the tip within one pyriform sinus (typically right side unless anatomy dictates).

• Confirm placement endoscopically; secure catheter (tape/holder) to prevent displacement.

• Connect to continuous low negative pressure suction (target –20 cmH_2O; adjust if needed for comfort and safety).

• Maintain suction continuously while catheter is in situ; nursing checks each shift for patency, position, skin/nasal integrity, and patient tolerance.

• Discontinue and remove catheter upon swallowing recovery, ICU discharge/transfer, or if clinically indicated due to intolerance/complication.

• Catheter not routinely changed unless clogged or displaced.

Providers: ICU nurses trained in the protocol; placement confirmed with ICU physician support as needed.

Location: ICU bedside.

Dose/intensity: continuous suction at low pressure for the duration of dysphagia management (typically several days; median around 5 days in the completed trial).

Adherence/fidelity: standardized checklist; daily documentation of suction pressure, hours of suction, catheter events (blockage/displacement), and any adverse effects.

Co-interventions: same standard dysphagia bundle in both groups; other ICU care per treating team.

Outcomes

Primary outcomes:

• Time to recovery of safe swallowing (days) from randomisation, defined as achieving a GUSS score of 20 (no dysphagia) and/or ability to tolerate oral intake as per protocol; patients who die before recovery are treated as non-recovered (censored/competing-risk handled in analysis).

• Incidence of silent aspiration during ICU stay, measured using the trial's predefined aspiration biomarker/test and sampling schedule (e.g., tracheal secretion biomarker assay) [insert exact assay name/cutoff if required].

Secondary outcomes:

• Incidence of aspiration pneumonia during ICU stay (clinical diagnosis based on predefined criteria).

• ICU length of stay (days) from randomisation to ICU discharge.

• 28-day all-cause mortality.

• 90-day all-cause mortality.

• Inflammatory markers: serum CRP (mg/L) and WBC ($\times 10^9$/L) measured using routine central laboratory methods at ICU day 5 (±1 day).

• Safety outcomes: catheter-related complications (nasal discomfort/bleeding, mucosal injury, displacement, blockage), and any serious adverse events judged related to the intervention.

Participant timeline (SPIRIT schedule)

Timepoint	Screening	Baseline (Day 0)	ICU Days 1–7	Day 5 (±1)	ICU discharge / Day 28	Day 90
Eligibility & consent	X	—	—	—	—	—
Randomisation	—	X	—	—	—	—
Standard care bundle	—	X	X	X	X	—
Pyriform sinus suction (intervention arm)	—	X	X (while in situ)	X	Stop if recovered/discharged	—
GUSS swallowing assessment	—	X	Repeated per protocol	—	At discharge/day28	—
Silent aspiration test/biomarker	—	Baseline if planned	Daily/periodic per protocol	—	—	—
Aspiration pneumonia assessment	—	—	Ongoing surveillance	—	X	—
CRP/WBC lab tests	—	Baseline if available	—	X	—	—
Adverse events	—	X	X	X	X	—

Mortality status	—	—	—	—	Day 28	Day 90

Sample size

The completed trial enrolled 112 participants (56 per group). The sample size was calculated a priori to provide adequate power to detect a clinically meaningful difference in swallowing recovery time and/or silent aspiration incidence, allowing for minimal attrition. Full assumptions (effect size, event rate, alpha, power) are available in the statistical analysis plan.

Recruitment

Consecutive eligible ICU patients were screened daily by the study team. Written informed consent was obtained from the patient when possible, or from a legally authorized representative.

Assignment of interventions

Allocation sequence generation

A computer-generated randomisation list was created using permuted blocks (block size 4) to ensure balance between groups.

Allocation concealment mechanism

Allocation was concealed using sequentially numbered, sealed, opaque envelopes prepared by a staff member not involved in participant enrolment or care.

Implementation

After eligibility confirmation and consent, the enrolling clinician opened the next envelope to assign the participant to intervention or control.

Blinding

Blinding of participants and treating staff is not feasible because the suction catheter is visible and requires care. To reduce bias, outcome definitions are objective and predefined (e.g., GUSS score thresholds, prespecified pneumonia criteria, laboratory markers), and statistical analyses are performed according to a prespecified SAP.

Data collection and management

Data collection methods

Baseline demographics, ICU admission diagnoses, severity scores (APACHE II, SOFA), ventilation duration, and baseline swallowing status (GUSS category) are recorded. Outcome data include daily swallowing assessments, aspiration testing results, pneumonia diagnosis, laboratory markers, ICU LOS, and mortality.

Data management

Data are entered into a password-protected electronic database with range checks. Identifiers are stored separately from analysis datasets. Only authorized study personnel have access. Data cleaning and locking procedures are defined in the SAP.

Confidentiality

All data are handled according to local regulations and institutional policies. Participant identifiers are removed from analysis datasets.

Statistical methods

Primary analyses follow the intention-to-treat principle. Time-to-event outcomes are analysed using Kaplan–Meier methods and Cox proportional hazards models. Binary outcomes are analysed using logistic regression, reporting odds ratios with 95% confidence intervals. A generalized pairwise comparison (GPC) framework is used for a prioritized global outcome assessment (90-day survival, ICU LOS, swallowing recovery time), reporting net benefit and a global Δ.

Monitoring

Harms

All adverse events potentially related to nasal catheter placement and suction (e.g., nasal bleeding, discomfort, mucosal injury, displacement, blockage) are recorded. Serious adverse events are reported to the ethics committee per institutional policy.

Auditing

Internal auditing is conducted by the study coordinator through periodic chart reviews and database checks. No external audit is planned.

Ethics and dissemination

The trial has ethics committee approval. Informed consent is obtained from all participants or surrogates. Results will be disseminated through peer-reviewed publication and conference

presentations. Anonymized data and analytic code may be shared upon reasonable request, subject to institutional approvals.