PROTOCOL

Title. Bedside nasojejunal short-peptide feeding versus conventional care in adults with acute respiratory distress syndrome and recent upper gastrointestinal bleeding: two-centre prospective observational cohort.

Design. Prospective observational cohort at two centres with parallel exposure groups defined by routine care: (a) bedside nasojejunal placement with short-peptide enteral nutrition; (b) conventional care without nasojejunal feeding (which may include whole-protein nasogastric feeding or delayed enteral nutrition). No randomisation or masking. Follow-up for nutritional outcomes to Day 7 and for clinical outcomes to ICU discharge, capped at 28 days.

Objectives. The objective is to evaluate whether early short-peptide enteral nutrition delivered via bedside nasojejunal tube is associated with improved 7-day nutritional recovery compared with conventional care without nasojejunal feeding, and to assess safety and feasibility in routine practice.

Endpoints. The primary endpoint is change in serum prealbumin from Day 1 to Day 7 measured by hospital biochemistry. Key secondary endpoints include change in serum albumin Day 1 to Day 7; C-reactive protein and interleukin-6 on Days 1, 4, and 7; lymphocyte count and nitrogen balance on Days 1 and 7; daily delivered energy and protein on Days 1–7; feeding intolerance, aspiration, and rebleeding to Day 7; ICU-acquired infections to ICU discharge or Day 28; ventilator-free days to Day 14; ICU length of stay; and 28-day mortality.

Population. Adults (≥18 years) with moderate–to–severe acute respiratory distress syndrome and a recent upper gastrointestinal bleed that has been clinically stable for at least 48 hours; require enteral nutrition and cannot take orally; anticipated ICU stay ≥72 hours. Key exclusions include ongoing or recurrent active bleeding at screening; known allergy or intolerance to short-peptide formula components; major gastrointestinal surgery or obstruction; palliative status with expected withdrawal of life-sustaining therapy within 48 hours. Site investigators apply local screening logs.

Exposure definitions. The nasojejunal short-peptide group receives bedside tube placement per local protocol with radiographic confirmation followed by continuous pump feeding of a short-peptide formula. The conventional-care group does not receive nasojejunal placement; usual care may include nasogastric whole-protein feeding or delayed feeding at the clinician's discretion. Exposure is classified within 24 hours of enrolment; cross-overs and delayed placements are recorded.

Procedures and assessments. Baseline demographics, ARDS severity indices, haemodynamics, and laboratory tests are abstracted from the record. Nutrition delivery is captured daily on Days 1–7. Laboratory markers follow the schedule above. Adverse events are monitored through Day 7. Clinical status, ventilator use, infections, and disposition are followed to ICU discharge or Day 28.

Sample size. The target is 400 participants (approximately 200 per group), selected to provide >80% power to detect a small-to-moderate standardised difference in the primary endpoint while enabling adjusted comparative analyses and prespecified subgroup assessments.

Safety monitoring. Because treatments are determined by usual care, risk is minimal. Procedure-related events (airway misplacement, arrhythmia, perforation) and nutrition-related complications are recorded and reported per institutional policy.

Ethics. Written informed consent or proxy consent is obtained per ICU practice. The study was approved by the Xiamen Chang Gung Hospital Ethics Committee and the Chang Gung Medical Foundation IRB and will be conducted in accordance with the Declaration of Helsinki and applicable regulations.

Dissemination. Results will be submitted to a peer-reviewed journal and summarised in plain English on the registry; de-identified data may be available on request after publication subject to ethics and privacy requirements.