Pediatric Critical Care Medicine
XXX 2026 • Volume 27 • Number 00 • Pages XX–XX

*PCCM* TRIAL

OPEN

# Protocol for a Randomized Clinical Trial to Evaluate Not Routinely Measuring Gastric Residual Volume to Guide Enteral Feeding Versus Routine Measurement in Mechanically Ventilated Critically Ill Children (GASTRIC-PICU)

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**OBJECTIVE:** Providing adequate nutrition is a key aspect of pediatric intensive care, with enteral administration preferred. The regular measurement of gastric residual volume (GRV) to guide feeding is common, but it results in frequent feed interruptions due to a perceived high GRV. The GASTRIC-PICU (GRV to guide enteral feeding vs. routine measurement in mechanically ventilated critically ill children) randomized controlled trial aims to evaluate the clinical and cost-effectiveness of not routinely measuring GRV to guide enteral feeding compared with the usual practice of routine measurement.

**DESIGN:** Multicenter, randomized, non-inferiority, open-label clinical trial with embedded health economic evaluation.

**SETTING:** Twenty-three PICUs across United Kingdom, Scotland, Northern Ireland, and Switzerland.

**PATIENTS:** Infants and children 37 weeks old or older corrected gestational age to 16 years admitted to participating PICUs, on mechanical ventilation and being enterally fed.

**INTERVENTION AND COMPARISON:** Standard feeding protocols without routinely measuring GRV to guide feeding will be compared against standard feeding protocols with routine (at least 6-hourly) GRV measurement to guide feeding.

**MEASUREMENTS AND MAIN RESULTS:** Randomization 1:1 between no routine GRV measurement and routine GRV measurement stratified by site, age at admission, and main reason for admission. "Research Without Prior Consent" will be used. The primary clinical outcome is a composite outcome of survival and days free from mechanical ventilation at 30 days (non-inferiority). The superiority co-primary outcome is the percentage of the child's estimated energy requirements achieved by 72 hours after randomization. The primary outcome of cost-effectiveness analysis is incremental net monetary benefits at 6 months. Baseline demographics and clinical status, daily nutritional data for the first 7 days, and discharge outcome, as well as longer-term survival and economic data will be collected.

**CONCLUSIONS:** Trial findings will be disseminated in peer reviewed journals, via international conferences and in lay language via social media.

**KEYWORDS:** child; critical care; enteral nutrition; feeding; neonate; pediatric intensive care; randomized clinical trial



DOI: 10.1097/PCC.0000000000003921

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## RESEARCH IN CONTEXT

- This randomized controlled trial (RCT) in the PICU will evaluate whether a long-standing nursing practice—routinely measuring gastric residual volume (GRV)—is necessary around the time of enteral feeding in mechanically ventilated children.
- A previous multicenter randomized clinical trial in adults showed that omitting this practice was non-inferior to routinely measuring GRV, with no adverse effect on outcomes.
- The design and implementation of the GASTRIC-PICU trial have been informed by extensive feasibility work involving both clinicians and families, enabling a pragmatic approach that includes a Research Without Prior Consent model.

Inadequate delivery of nutrition is a problem in children managed on the PICU, with multicenter international data from 2012 indicating that only 37% of them received the recommended energy intake (1). During critical illness, poor energy intake is associated with prolonged mechanical ventilation, impaired wound healing, increased healthcare-acquired infections, longer PICU stays, and increased mortality (1–6). In high resource settings, such as the United Kingdom, most children survive critical illness (7) and so reducing these complications of inadequate nutrition is important.

Interruption to enteral nutrition in mechanically ventilated children is the most preventable reason for inadequate energy delivery (8, 9). Clinical practice in the United Kingdom includes 4–6 hourly aspiration of gastric tubes to measure the gastric residual volume (GRV) (10). Large GRV volumes prompt interruption of feeding, despite a lack of evidence of the relationship between increased aspirate volumes and feed intolerance (10). Clinical staff's rationale for GRV measurement is mitigating a potential risk of aspiration (11, 12). This solution may not be valid (13, 14). For example, a systematic review in critically ill adults failed to find evidence that measuring GRV reduced the risk of aspiration or ventilator-associated pneumonia (VAP) (15). Volumes of gastric aspirate obtained through aspiration correlate poorly with other measures of GRV (16, 17) since aspiration volumes are affected by patient (e.g., body position and viscosity of stomach contents) and clinical factors (e.g., feeding tube size, and syringe size used to aspirate) (16). We also know that in children practice varies widely across Europe (18). Furthermore, in a randomized controlled trial (RCT) of mechanically ventilated adults, not measuring GRV was non-inferior to regular residual GRV monitoring of VAP (14).

Therefore, since the routine practice of GRV monitoring to guide enteral feeding in critically ill children is not based on evidence from critically ill children, as opposed to adults, it was clear that a robust clinical trial in critically ill children was needed.

## METHODS

### Primary Objective

To determine whether no routine GRV measurement is non-inferior to routine (at least 6 hourly) GRV measurement to guide enteral feeding in critically ill ventilated children in terms of a composite outcome of survival and days free from mechanical ventilation and superior in terms of energy target achievement (superiority). The primary health-economic objective was to evaluate the incremental net monetary benefit of no routine GRV measurement.

### Design and Setting

The GASTRIC-PICU study is a multicenter, noninferiority, open-label RCT with a health economic evaluation conducted across 22 National Health Service (NHS) PICUs in the United Kingdom (England, Scotland, and Northern Ireland) and one PICU in Switzerland.

### Screening and Randomization

Patients admitted to a participating PICU will be screened against the eligibility criteria by the local clinical team. Eligible children (**Table 1**) will be randomized 1:1 to either intervention (no routine GRV measurements) or control (routine GRV measurements) using online application software (**Supplementary file**, https://links.lww.com/PCC/C710). Allocation will be stratified by site, age at admission (younger than 1 mo, 1 mo old or older to younger than 12 mo, 12 mo old or older), and the main reason for admission (structural disease of the heart vs. other). Randomization must occur within 24 hours of first meeting all inclusion criteria. The intervention will be delivered by clinical nursing staff.

### Intervention and Concomitant Care

Following randomization, treatment will start immediately. For patients randomized to the intervention group, GRV will not be routinely measured. Feed intolerance will be assessed using clinical signs only (e.g., vomiting), although GRV will be acceptable in certain situations (e.g., ahead of a procedure or severe deterioration) (Supplementary file, https://links.lww.com/PCC/C710). For patients in the control group, routine GRV measurements will be taken at least every 6-hours to guide enteral feeding, alongside clinical signs. All other feeding practices will follow local protocols. Adherence to the study allocation and protocol will be monitored throughout the trial by regular review of the data. Findings will be communicated to research staff through routine reports, meetings, and site monitoring.

### Consent Procedures

Due to early (within 6 hr) initiation of feeding in U.K. PICUs (10), prospective consent is deemed not appropriate to be used, because the ability of parents to provide informed consent at this time could be impaired. Therefore, we will adopt Research Without Prior Consent (RWPC) approach (19). This model, developed in line with the CONseNt methods in pediatric Emergency and Urgent Care Trials study guidance (19), has been shown to be acceptable to parents and clinicians in other U.K. RCTs in PICUs (20, 21). It is legislated in European Union countries and the United Kingdom when certain conditions are met (e.g., urgent treatment required). In this approach permission is sought to use data that has already been collected and consent for the child to continue to take part in the trial (20).

Once randomized into the study, a trained member of the site research team will approach the parents/legal guardians as soon as it's appropriate (usually within 24–48 hr). A Participant Information Sheet will be provided. A modified procedure will be followed for 1) children in care of the local authority (Supplementary file, https://links.lww.com/PCC/C710), 2) where discharge occurs before consent issought, or 3) the child

## TABLE 1.
### Eligibility Criteria For Participant Inclusion and Exclusion

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| Infants and children 37 wk old or older corrected gestational age and less than 16 yr at the time of randomization<br>Enrolled within 24-hr of first meeting all the following criteria:<br>Receiving invasive mechanical ventilation (with extubation not planned in the next 48-hr)<br>Intention to start feeding or started feeding via the gastric route (including gastrostomy) | Post-pyloric feeding or jejunostomy<br>End-of-life care plan in place with limitation of resuscitation<br>Children on long term invasive mechanical ventilation<br>Current or recent gut pathology or surgery (e.g., necrotizing enterocolitis, active gastrointestinal bleeding, or any intestinal surgery)<br>Known to have been enrolled in the GASTRIC-PICU trial in the last 6 mo |

dies before consent is sought. If no consent is obtained before discharge or death, a letter will be sent to parents/guardians and if no objection is received within four weeks, data will be retained. Where a participant has a National Data Opt-out in place, only non-identifiable data will be retained.

A modified consent procedure will apply to Swiss participants: both the prospective and RWPC model will be used. Data will not be retained from patients for whom explicit consent is not obtained (i.e., discharged or died before consent being sought) and when RWPC model is used but parents decline.

### Safety Monitoring

Adverse event (AE) reporting will follow the Health Research Authority (HRA) guidelines on studies which do not use Investigational Medicinal Products (22). Key safety outcomes are VAP (23) and necrotizing enterocolitis (NEC) (24). They will be captured via the case report forms (CRFs) and will not need to be reported as serious adverse events (SAEs). SAEs will only be reported if they are possibly, probably or definitely causally related to the study (i.e., a consequence of not measuring or measuring GRV). NEC, pulmonary aspiration/VAP, and vomiting will be considered expected AEs. Non-SAEs will not require reporting (**Fig. 1**; and Supplementary file, https://links.lww.com/PCC/C710).

Safety information will be sent to the Data Monitoring and Ethics Committee (DMEC) on a basis deemed appropriate by the DMEC.

### Questionnaire Follow-Up

At 6 months, parents/legal guardians will be emailed or posted (as requested at the time of consent) a questionnaire pack by the Intensive Care National Audit and Research Centre Clinical Trials Unit (ICNARC CTU) containing the Pediatric Quality of Life Score (PedsQL) (25), CHU-9D (Child Health Utility for participants older than 5 yr) (26), which will include a feeding status question (from the Functional Status Score) (27), and a Health Services Questionnaire (HSQ). Electronic questionnaires will be sent via an online survey platform Smart Survey. Survival status will first be ascertained through review of medical records by local research teams or via linkage with nationally held records. Non-responders will be contacted by phone to offer alternative completion methods.

Follow-up for Swiss participants will be coordinated by the Swiss team. Those parents will not receive the HSQ, however, all other questionnaires will remain the same.

### Approvals

GASTRIC-PICU received the U.K. HRA and ethical approval from the London–Bloomsbury Research Ethics Committee on May 10, 2023 (reference number 23/LO/0284). The trial was registered at the U.K. clinical study registry (https://www.isrctn.com; reference 79668198) on April 5, 2023 and the Swiss National Clinical trial Portal (SNCTP000006200). The trial will be conducted in accordance with the approved trial protocol, the Institute of Child Health Good Clinical Practice guidelines, the Declaration of Helsinki of 1975, the U.K. Data Protection Act of 2018 (registration number Z6289325), as well as ICNARC CTU's research policies and procedures (28–30).

Consent will be obtained from the parents/legal guardians before collecting identifiable data. If informed consent cannot be obtained (i.e., participants discharged or died before consent is received), we will collect these data under the provisions of Section 251 of the NHS Act 2006 for U.K. participants only, as approved by the Confidentiality Advisory Group on May 12, 2023.

## OUTCOME MEASURES

### Primary Outcome

The two clinical effectiveness co-primary outcomes are: 1) a composite outcome of survival and days free from mechanical ventilation at 30 days (non-inferiority), and 2) the percentage of the child's estimated energy requirements achieved by 72 hours (superiority) (Supplementary file, https://links.lww.com/PCC/C710). These co-primary outcomes were chosen because feasibility work in the United Kingdom demonstrated that clinicians were most concerned about pulmonary aspiration (and consequent VAP) if not measuring GRV and demonstration that not measuring GRV was not unacceptably worse (non-inferior) was needed before any practice change. As most U.K. PICUs did not have a robust and ongoing surveillance program around VAP, duration of mechanical ventilation was chosen, as any clinically

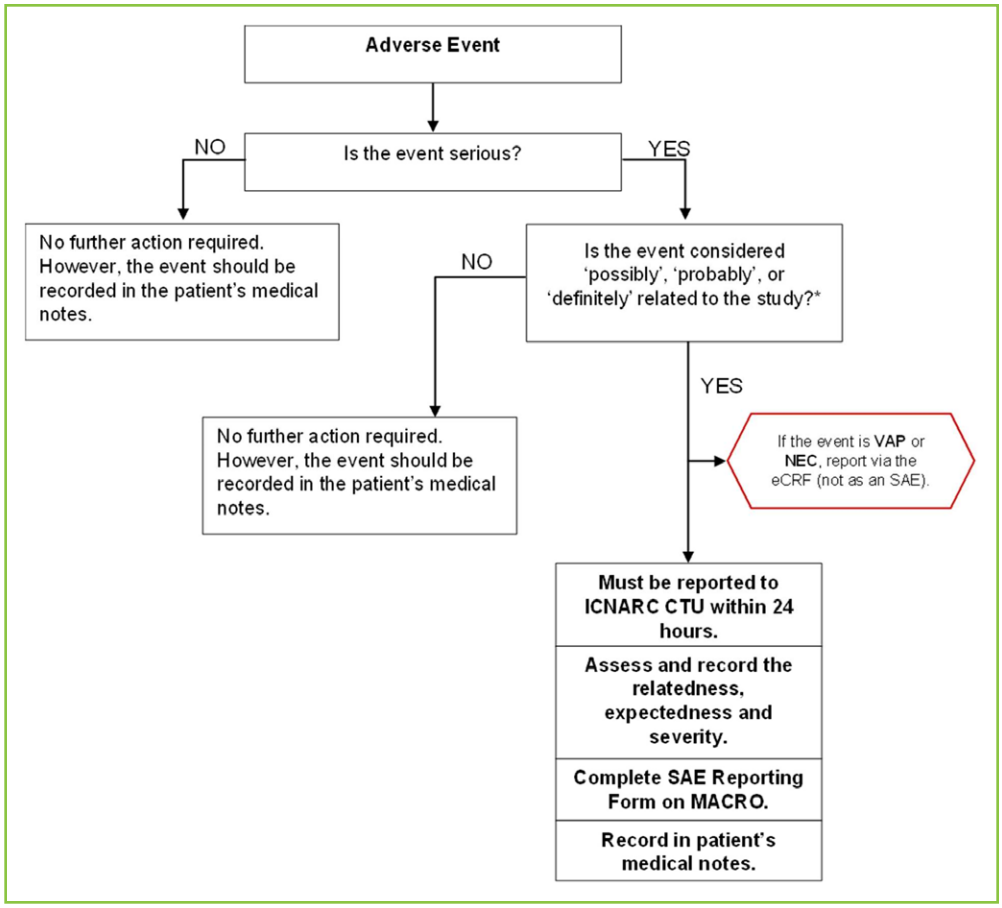


**Figure 1.** Adverse event reporting. eCRF = electronic case report forms, ICNARC CTU = Intensive Care National Audit and Research Centre Clinical Trials Unit, MACRO = Clinical Trial Management Software, NEC = necrotizing enterocolitis, SAE = serious adverse event, VAP = ventilator associated pneumonia.

significant aspiration would prolong the time course of invasive mechanical ventilation, and this was a robust measure to collect. It was also deemed important to understand the impact of not routinely measuring GRV on nutritional outcomes. Both North American (American Society of Parenteral and Enteral Nutrition) (31) and European evidence-based guidelines (32) recommend aiming for a target of 65% of estimated energy requirements (estimated by the Schofield Equation [33]) by 72 hours after PICU admission. Therefore, this endpoint was chosen for the superiority outcome. A full list of trial outcomes is provided in **Table 2**.

### Data Collection

Data will be collected at baseline (before randomization), daily for the first 7 days, at discharge from PICU, and 30 days and 6 months following randomization on an online database (**Table 3**; and Supplementary file, https://links.lww.com/PCC/C710). Data entry staff will be trained, and data will be monitored by the trial team as per the protocol. The trial will also use routinely collected data from Pediatric Intensive Care Audit Network (PICANet), which carries out clinical audit of all PICUs in the United Kingdom. These data will include baseline demographics, severity of illness scores, and daily critical care interventions (Supplementary file, https://links.lww.com/PCC/C710). Data collected at the Swiss PICU will not be linked to either the NHS or the PICANet.

## STATISTICAL METHODS

### Sample Size Calculation

For the composite outcome, a non-inferiority margin of an upper limit for the odds ratio of 1.2 was selected (corresponding to a 0.8% absolute increase in mortality and a 12-hour difference in median duration of ventilation). In a survey of U.K. PICU clinicians this margin was preferred because it would have a meaningful impact on duration of PICU admission and it is a change that would be highly relevant to patients/families. To have 90% power to detect non-inferiority, based on the upper limit of a two-sided 95% CI excluding this margin, and using an outcome distribution estimated from the SANDWICH (sedation and weaning in children) trial (i.e., 4.2% mortality and log-normal distribution for duration of ventilation with median 2.9 d and lower quartile 1.0 d) (34) requires a total evaluable sample size of 4000. To retain power for a per-protocol (PP) analysis we have allowed for crossover of 10% and withdrawal of 5%, to set a total target size of 4700.

## AT THE BEDSIDE

- A systematic review in critically ill adults failed to find evidence that measuring GRV reduced the risk of aspiration or ventilator-associated pneumonia when feeding mechanically ventilated patients.
- In this first large RCT in the PICU we will evaluate the effectiveness of routinely measuring GRV in mechanically ventilated children, with the aim of addressing an important evidence gap in clinical practice.
- If our trial demonstrates that not routinely measuring GRV is non-inferior to routine measurements, it could lead to a change in clinical guidelines regarding GRV monitoring.

The percentage of the child's predicted energy requirements achieved by 72 hours after randomization was anticipated to be approximately normally distributed, with SDs within each group between 20% and 40% (18). Due to uncertainty in the SD, a blinded sample size re-measurement was undertaken at the interim analysis timepoint, according to a pre-specified statistical analysis plan. The sample size in the intention-to-treat (ITT) population required to provide 90% power at $p$ value of less than 0.05, two-sided to detect a 4% absolute difference in energy intake based on the observed pooled SD was 2258. This effect size was chosen to detect a small (Cohen's d 0.2) to very small (Cohen's d 0.1) effect based on the anticipated range of the SD.

### Internal Pilot

An internal pilot will run for 10 months (approximately 1500 participants) to assess key progression criteria regarding site opening, recruitment, and adherence to the study protocol. The pilot will follow the same processes as the main trial, and participants enrolled will be included in the analysis of the main trial.

**TABLE 2.**
**Trial Outcome Measures**

| Type of Outcome | Outcomes |
|---|---|
| Primary clinical outcomes | Composite outcome of survival and days free from mechanical ventilation at 30 d from randomization (non-inferiority), and<br>Percentage of the child's estimated energy requirements achieved by 72 hr after randomization (superiority) |
| Primary cost-effectiveness outcome | Incremental net monetary benefits at 6-mo |
| Secondary outcomes during PICU stay | Time to achievement of target energy requirement<br>Time to achievement of target protein requirement<br>Diagnosis of ventilator associated pneumonia<br>Diagnosis of necrotizing enterocolitis in infants<br>Duration of time with no enteral feed in the first 7-d after randomization<br>Incidence of vomiting leading to feed stoppage in the first 7 d after randomization<br>Documented healthcare acquired infections |
| Secondary outcomes assessed at PICU discharge | Length of PICU stay (d) |
| Longer terms secondary outcomes (post-PICU discharge) | Mortality at 30-d and 6-mo post-randomization<br>Length of hospital stay<br>Health-related Quality of Life (assessed using pediatric Quality of Life Inventory and Child Health Utility-9D questionnaire data)<br>Quality-Adjusted Life Years<br>Healthcare resource use and costs<br>Feeding component of the Functional Status Score |

### Interim Analysis

A single interim analysis will be performed after randomization and 30-day follow-up of 50% of the target sample size. The composite primary endpoint will be compared between groups and the trial will be stopped early if a significant difference is seen (in either direction), using a Peto-Haybittle stopping rule of *p* value of less than 0.001.

### Clinical Effectiveness Analysis

All analyses will be lodged in a statistical analysis plan, a priori, before the investigators are unblinded to any trial outcomes. Baseline characteristics will be compared between the two groups to observe balance but will not be statistically tested. The ITT population excludes patients who requested removal of all data. The PP population additionally excludes patients classed as non-adherent or found to be ineligible following randomization. For secondary outcomes, ITT and PP populations additionally exclude patients where consent to data collection has been withheld or withdrawn before the outcome timepoint.

The clinical co-primary composite outcome will be analyzed using a proportional odds logistic regression model, with death during the first 30-day following randomization ranked as the worst outcome and surviving patients assigned values according to their total calendar days free from mechanical ventilation during the first 30 calendar days following randomization. The model will be adjusted for important baseline variables, defined a priori based on an established relationship with outcome for critically ill children, and all variables used as stratification variables at randomization. The primary effect estimate will be the adjusted OR, which will be calculated in both the ITT and PP populations with two-sided 95% CIs. If the upper limit of the CI is not more than 1.2 in both the ITT and PP populations, we will declare the intervention is noninferior with respect to mortality and days free of mechanical ventilation at 30 days. Secondary analyses will test the same outcome for superiority/inferiority. The two separate components of the composite primary outcome will also be reported by group.

The co-primary superiority outcome will be analyzed using a linear regression model adjusted for the same baseline variables as the clinical co-primary outcome. The primary effect estimate will be the difference in mean percentage of target achieved between the groups in the ITT population, which will be tested for superiority and reported with a two-sided 95% CI. Both co-primary outcomes will be reported in a limited number of clinically relevant subgroups, which will include patients classified by age (44 wk old or younger vs. older than 44 wk of gestation) and reason for admission (cardiac, respiratory, and other). An interaction term between subgroup and treatment group will be added to the regression models.

All secondary outcomes will be reported in both the ITT and PP populations unless otherwise specified. Time-to-event outcomes will be analyzed using Cox proportional hazards regression. Patients who do not achieve their target will be censored at death, discharge from PICU, or on day-7 following randomization (whichever is earliest). Binary endpoints will be compared using adjusted logistic regression. Diagnosis of VAP will additionally be reported as a rate per 1000 hours of ventilation and analyzed using Poisson regression. Continuous endpoints will be analyzed using adjusted linear regression. The feeding component of Functional Status Score will be analyzed as an ordinal endpoint using adjusted proportional odds regression.

### Integrated Health Economic Evaluation

The cost effectiveness analysis (CEA) will take a health and personal health services perspective as recommended by the National Institute for Health and Care Excellence (35). It will measure resource use associated with the interventions, PICU and hospital length of stay, and follow-up visits to hospitals, primary and community care services. Resource use associated with the interventions (e.g., disposables for GRV) will be measured from data collected in the CRFs and informed by expert clinical opinion. Resource use data from the PICU and hospital will be taken from the CRFs and linked to routine data from PICANet and through completion of the HSQ. Use of primary care and community care services will be assessed through the HSQ. Resource use data will be valued using appropriate unit costs from the NHS payment by results and Personal Social Services Research Unit databases to calculate total costs per patient for up to 6 months. Health related quality of life (HRQoL) will be measured using age appropriate PedsQL at 6 months. Responses will be mapped into preference-based CHU-9D score to estimate preference weighted HRQoL. HRQoL and

**TABLE 3.**
**Summary of Data Collection**

| Data | Baseline | Day 3 (72 hr) | Day 7 | PICU discharge | Day 30 | Hospital Discharge | Month 6 |
|---|---|---|---|---|---|---|---|
| Demographics | X | | | | | | |
| Energy/protein targets | X | X | | | | | |
| Enteral feeding data | | X | X | | | | |
| Feed tolerance data (e.g., vomiting) | | X | X | | | | |
| Diagnosis of ventilator-associated pneumonia | | | | | X | | |
| Diagnosis of necrotizing enterocolitis | | | | | X | | |
| Healthcare-associated infections | | | | | X | | |
| Safety reporting | | X | X | X | X | | |
| Length of stay | | | | X | | X | |
| Mortality | | | | | X | | X |
| Pediatric Quality of Life Inventory, Child Health Utility-9D (Quality of Life score) | | | | | | | X |
| Feeding component of the Functional Status Score | | | | | | | X |
| Health Services Questionnaire | | | | | | | X |

survival data will be combined to report quality of life years (QALYs). The CEA will follow the ITT principle and report the mean (95% CI) incremental costs, QALYs and net monetary benefit at 6 months. The CEA will use appropriate multilevel regression methods and adjust for key baseline covariates as per the primary clinical analysis. Missing data will be imputed using multiple imputation methods. The economic analysis will also perform a cost-consequence analysis and report incremental costs alongside primary clinical outcome at 30 days.

Data from the University Children's Hospital Zurich will not be used for the economic analysis.

## GOVERNANCE AND OVERSIGHT

### Confidentiality

Limited identifiable data will be required to successfully follow-up participants by ICNARC CTU staff and enable linkage to PICANet. ICNARC CTU will preserve participant confidentiality and not disclose or reproduce any information by which a participant could be identified. Swiss data will be handled according to Swiss Law and will only be accessible to authorized personnel who require the data to fulfill their duties within the scope of the research project.

### Patient and Public Involvement

Feasibility work with former PICU parents and former patients was extensive (12, 21). One PPI representative is a co-investigator and a member of TMG, and they have been fully involved in the trial development. In addition, independent PPI representative(s) are members of the Trial Steering Committee (TSC).

### Oversight

The TMG is responsible for the management of the trial and meets regularly to monitor its conduct and progress. It is led by the Chief Investigator and includes the co-investigators and the ICNARC CTU trial team. GASTRIC-PICU is managed by the ICNARC CTU in accordance with the Medical Research Council's Good Research Practice: Principles and Guidelines (28), which is based on the ICH-GCP principles (29) and the U.K. Department of Health's Policy Framework for Health and Social Care Research (30). The on-site monitoring plan follows a risk-based strategy. A

majority-independent TSC has been established to monitor trial progress and an independent DMEC to monitor safety and outcomes, that is, to review interim analysis results and to recommend continuing/stopping the trial (Supplementary file, https://links.lww.com/PCC/C710).

### Trial Status

This article presents the study protocol (v4.0), dated February 7, 2025 (see https://www.isrctn.com/ISRCTN79668198). The first participant was recruited in June 2023. The study progressed to a full trial after the internal pilot phase and completed recruitment in December 2025. The study will be disseminated through publication in peer-reviewed medical journals, at international conferences and via social media.

## ACKNOWLEDGMENTS

The authors thank the research and clinical teams at the participating sites: Addenbrooke's Hospital (Cambridge), Alder Hey Children's Hospital (Liverpool), Birmingham Children's Hospital, Bristol Royal Hospital for Children, Great Ormond Street Hospital (CICU and PICU, London), John Radcliffe Hospital (Oxford), Leicester Royal Infirmary, Nottingham Children's Hospital, Royal Brompton Hospital (London), Southampton Children's Hospital, St Mary's Hospital (London), St George's University Hospital (London), Sheffield Children's Hospital, Royal Manchester Children's Hospital, Evelina London Children's Hospital, the Royal London Hospital, Staffordshire Children's Hospital at Royal Stoke, Leeds Children's Hospital, Newcastle Freeman Hospital, Royal Hospital for Children (Glasgow), University Children's Hospital (Zurich, Switzerland), Great North Children's Hospital (Newcastle), Royal Belfast Hospital for Sick Children.

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*Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (http://journals.lww.com/pccmjournal).*

*Drs. Tume and Peters served as Chief Investigators. Marzena Orzol and Irene Chang were the Trial Managers. Emma Laing was the Senior Trial Manager. Dr. Edwards contributed as the Senior Statistician. Paloma Ferrando-Vivas contributed as the Trial Statistician. Dr. Tume, Marzena Orzol, and Irene Chang drafted the article. Dr. Harrison, Lynne Latten, Dr. Menzies, Dr. Marino, Dr. Brown, Dr. Hall, Dr. Woolfall, Dr. Sadique, Dr. Veale, Dr. Schlapbach, Paul Mouncey, and Dr. Valla were trial co-applicants and members of the Trial Management Group. Lamprini Lampro, Julie Camsooksai, Jahara Khatun, Millie Parke, Hannah Sedgwick, and Carly Au supported management of the trial. All authors read and approved the final article.*

*The Intensive Care National Audit and Research Centre (ICNARC) was the trial sponsor.*

*Dr. Marino has received honorarium to give lectures for Abbott Laboratories, Danone and Nestle, who had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the article; or in the decision to publish the results. For the remaining authors none were declared. Marzena Orzol's, Dr. Edwards', Paloma Ferrando-Vivas', Lynne Lampro's, Millie Parke's, Hannah Sedgwick's, Dr. Harrison's, Dr. Hall's, and Paul Mouncey's institutions received funding from the National Institute for Health and Care Research (NIHR). Marzena Orzol, Dr. Peters, Dr. Edwards, Paloma Ferrando-Vivas, Julie Camsooksai, Jahara Khatun, Millie Parke, Carly Au, Dr. Harrison, Dr. Brown, Dr. Hall, Paul Mouncey, and Dr. Tume received support for article research from the NIHR. Irene Chang's*

*institution received funding from the NIHR Health Technology Assessment program (HTA) (NIHR133835). Dr. Peters', Julie Camsooksai's, Dr. Brown's, and Dr. Tume's institution received funding from the NIHR HTA. Dr. Marino received funding from Abbott Laboratories, Danone/Nutricia, and Nestle. Dr. Valla received funding from Baxter, Nutricia, and Nestle Health Science. The remaining authors have disclosed that they do not have any potential conflicts of interest.*

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