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No routine measurement of gastric residual volume in paediatric critical care

Submission date
07/02/2023

Recruitment status
No longer recruiting

Registration date
05/04/2023

Overall study status
Ongoing

Last Edited
14/10/2025

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Most children in intensive care cannot eat normally by mouth and require feeding into their stomach via a tube (a nasogastric (NG) tube or gastrostomy). It is important to provide enough calories to children through their feeds while they are critically ill, as this can help them to get off the ventilator faster, improves how quickly wounds heal and generally helps them to recover better from their illness. Ensuring children in intensive care have enough calories from feeds is a big challenge. We know from large worldwide studies that most children in intensive care get only around half of the calories they need. This is mainly due to their feeds being stopped. The most common reason is that the amount of fluid in the stomach is felt to be 'large'. Across the UK, it is a common practice in all Paediatric Intensive Care Units (PICU) for nurses to check how much food is in the stomach. A syringe is attached to the end of the feeding tube and the child's stomach contents are gently 'sucked out'. This is to see how much fluid is in the child's stomach and see how well the child is digesting their feed. This is called the gastric residual volume or GRV, often referred to as an 'aspirate'. If a child has a 'large' GRV, often feeding is stopped. However, the amount of fluid in the child's stomach is affected by many things, not just how much we feed them, but also how much gastric juice their stomach produces and some of the medicines we use slow down the stomach's actions. The measurement of this (GRV) through the NG tube or gastrostomy is known to be quite inaccurate. Therefore, a decision may be taken to stop feeds, or not to increase feeds, when there is no need to. We do not know whether it is better to measure GRV routinely or not and this is why we are doing this study. This study aims to determine the clinical and cost-effectiveness of no routine GRV measurement to guide enteral feeding and to determine if it is non-inferior to standard at least 6 hourly GRV measurements in mechanically ventilated children admitted to PICU.

Who can participate?
Children who are mechanically ventilated and tube fed, who are aged at least 37 weeks corrected gestational age and less than 16 years

What does the study involve?
Half of the children in the study will be assigned to the routine GRV group where their stomach contents will be measured at least every 6 hours, the common practice in most paediatric intensive care units in the UK to control for feed intolerance or the stomach getting too full. The

other half of the children will not have this done and instead will be monitored for feed intolerance/stomach fullness using clinical signs only.

What are the possible benefits and risks of participating?
While the research team cannot guarantee that taking part in this study will benefit the participants, they may receive more of their required calorie (energy) needs from their feeds, which is important for recovery and reducing the length of illness. Also, by being in this study there will be a more detailed observation of the child's calorie and feed intake, along with other things such as the time they spend on the breathing machine. If a child is selected to have their GRV measured, they will be receiving standard UK care, so there will be no difference from 'usual care'. If a child is chosen at random to 'no GRV measurement' the risk is that the child's stomach might get full, and they might vomit and inhale this vomit into their lungs. However, this risk has never been proven. There is also a risk that when GRV is aspirated and returned into the child's stomach, this may also cause vomiting. This will not take place in the no GRV group. Small studies have not found any additional risks in children who did not have their GRV measured regularly, and in some countries (France) GRV is not routinely measured.

Where is the study run from?
The study is coordinated by Intensive Care National Audit and Research Centre (ICNARC) CTU (UK)

When is the study starting and how long is it expected to run for?
September 2022 to June 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Irene Chang (Trial Manager), irene.chang@icnarc.org

Contact information

Type(s)
Principal investigator

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Scientific

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
322370

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54988, IRAS 322370

Study information

Scientific Title

A randomised controlled trial of no routine gastric residual monitoring to guide enteral feeding in paediatric intensive care units.

Acronym
GASTRIC-PICU

Study objectives
GASTRIC-PICU study aims to identify if no routine measurement of gastric residual volume (GRV) to guide enteral feeding in paediatric intensive care units is non-inferior to the regular measurement of GRV at least 6 hourly in terms of clinical and health economics outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/05/2023, London-Bloomsbury REC (3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207104828; bloomsbury.rec@hra.nhs.uk), ref: 23/LO/0284

Study design
Randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oral and Gastrointestinal

Interventions
GASTRIC-PICU is a multi-centre, randomised, noninferiority, open-label trial with an internal pilot phase (with clear stop/go progression criteria to full trial) and health economic evaluation and patient follow-up at 6 months. A randomised controlled trial (RCT) design was chosen as this is the gold standard design for clinical trials.

The GASTRIC-PICU trial aims to determine the clinical and cost-effectiveness of no routine gastric residual volume (GRV) measurement to guide enteral feeding and to determine if it is non-inferior to standard at least 6 hourly gastric residual volume measurements in mechanically ventilated children admitted to PICU. The primary clinical objective is to determine whether no routine GRV measurement is non-inferior to at least 6 hourly GRV measurements to guide enteral feeding in critically ill ventilated children in PICU in terms of a composite outcome of survival and days free from mechanical ventilation (non-inferiority) and superior in terms of achievement of their estimated energy requirement (superiority).

The primary health-economic objective is to conduct a full economic evaluation to assess the relative cost-effectiveness of these two practices. Secondary objectives are to compare the non-routine measurement with regular up to 6 hourly measurements in terms of other important patient and family-centred outcomes and costs.

We will include 4,700 patients from at least 19 paediatric critical care units. The study will use a deferred consent model due to the emergency nature of the patient population. Eligible patients will be randomised by the PICU and their parents or legal guardians will be approached for consent to continue in the study at the earliest appropriate opportunity.

Eligible patients will be randomised to one of two study arms:
1. Intervention arm - no routine GRV measurement to guide enteral feeding. Patients in this study arm will be monitored for signs of feed intolerance using clinical signs only: vomiting and other gastrointestinal or systemic signs but not by using GRV.
2. Control arm - routine (at least 6 hourly) GRV measurements to guide enteral feeding. Patients in this study arm will be monitored for feed intolerance using the GRV measurements as well as vomiting, and other gastrointestinal or systemic signs.
All other clinical care for patients in both treatment groups will be determined by the clinical team responsible for the patient's care. Data will be collected daily whilst in PICU to describe the intensity and duration of treatment, alongside routine data collection. Patients will be followed up after 6 months to ascertain their quality of life. One interim analysis will be undertaken to check for evidence of significant harm or benefit.

INTERNAL PILOT
The internal pilot phase will last for ten months and will assess key progression criteria using a traffic light system. Key progression criteria will include site opening, patient recruitment, and treatment adherence. The same processes as the main RCT will be used throughout the internal pilot phase, with all patients recruited in the ten-month period included in the final analysis.

INDEPENDENT COMMITTEES
Both a Trial Steering Committee and an independent Data Monitoring & Ethics Committee (DMEC) will be convened and will meet regularly during the trial. The DMEC will monitor recruitment and retention, protocol adherence (including adherence to treatment protocols) and patient safety (including serious adverse events) and will review the interim analysis.

TIMELINE
Funding has been obtained from the NIHR for a 42-month period:
Months 1-6: Study set-up: all approvals & preparation for the start of the trial (site sign-up and local approvals, production of materials for participating sites, conducting site initiation meetings)
Months 7-40: Recruitment/follow-up period
Months 7-16: Internal pilot stage
Month 17: First annual REC report
Month 13: First follow-up questionnaires sent
Month 18: Second DMEC and TSC meetings to review internal pilot analysis Internal pilot report submitted to NIHR HTA
Month 32: Close to recruitment
Month 38: Final follow-up questionnaires
Months 39-42: Analysis and dissemination
Month 40: Database lock for primary analysis (clinical and economic evaluation) Commence primary analysis and write up
Month 40: Lock database for longer-term outcomes
Month 42: Submit primary outcome paper Collaborators' meeting Final DMEC and TSC meetings
Month 42: Submit longer-term outcomes paper and draft final report to NIHR

Intervention Type

Other

Primary outcome(s)
1. Composite outcome of survival and days free from mechanical ventilation measured using patient medical records at 30 days (non-inferiority)
2. Percentage of the child's estimated energy requirements achieved by 72 hours after randomisation (superiority) measured using patient medical records and Schofield equation at 72 hours post-randomisation
3. Incremental net monetary benefits at six months (cost-effectiveness analysis) measured using health care services questionnaire and patient medical notes at 6 months post-randomisation

Key secondary outcome(s))
1. Time to the achievement of target energy requirement measured using patient medical records and Schofield equation at 72 hours post-randomisation
2. Time to the achievement of target protein requirement measured using patient medical records at 72 hours post-randomisation
3. Diagnosis of ventilator-associated pneumonia (VAP) measured using patient medical records at 30 days post-randomisation
4. Diagnosis of necrotising enterocolitis (NEC) in infants – using patient medical records at 30 days post-randomisation
5. Duration of time with no enteral feed in the first 7 days after randomisation measured using patient medical records at 7 days
6. Incidence of vomiting leading to feed stoppage in the first 7 days after randomisation measured using patient medical records at 7 days
7. Documented healthcare-acquired infections measured using patient medical records at 30 days post-randomisation
8. Length of PICU stay and hospital stay measured using patient medical records at 30 days and 6 months post-randomisation
9. Mortality at 30 days and 6 months measured using patient medical records at 30 days and 6 months post-randomisation
10. Resource use and costs measured using Health Care services questionnaires at 6 months
11. Health-related quality of life measured using the pediatric quality of life inventory (PedsQL) and the validity of the child health utility instrument (CHU9D) questionnaire data at 6 months post-randomisation
12. Quality-adjusted life years (QALYs) measured using PedsQL and CHU-9D questionnaire data at 6 months post-randomisation
13. Feeding measured using the feeding component of the Functional Status Score at 6 months post-randomisation

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 20/05/2024:
1. Aged > = 37 weeks corrected gestational age and < 16 years at the time of randomisation
2. Enrolled within 24 hours of first meeting all the following criteria:
2.1. Receiving invasive mechanical ventilation (with extubation not planned in the next 48 hours)
2.2. Intention to start feeding or started feeding via the gastric route (including gastrostomy)

Previous participant inclusion criteria:
1. Aged > = 37 weeks corrected gestational age and < 16 years at the time of randomisation
2. Receiving invasive mechanical ventilation (with extubation not planned in the next 48 hours)
3. Intention to start feeding via the gastric route (including gastrostomy)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
37 weeks

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Post-pyloric feeding or jejunostomy
2. End-of-life care plan in place with limitation of resuscitation
3. Children on long-term mechanical ventilation
4. Current or recent gut pathology or surgery (e.g., necrotising enterocolitis (NEC), active GI bleeding, or any intestinal surgery)
5. Known to have been enrolled in the GASTRIC-PICU trial in the last 6 months

Date of first enrolment
29/06/2023

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
Kings College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre

Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Freeman Road Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
St Georges Hospital
Blackshaw Road
Tooting

London
United Kingdom
SW17 0QT

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Queens Medical Centre
Derby Road
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NG7 2UH

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street

Leeds
United Kingdom
LS9 7TF

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
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United Kingdom
BT9 7AB

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Sheffield Childrens NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
NHS Staffordshire and Stoke-On-Trent Integrated Care Board
1 Staffordshire Place
Stafford
United Kingdom
ST16 2LP

Study participating centre
Alder Hey Childrens NHS Foundation Trust
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre
The Royal Belfast Hospital for Sick Children
274 Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
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CF14 4XW

Sponsor information

Organisation
Intensive Care National Audit & Research Centre

ROR
https://ror.org/057b2ek35

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from GASTRIC@icnarc.org

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.0	07/02/2025	09/06/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes