ISRCTN42110505 https://doi.org/10.1186/ISRCTN42110505

A feasibility study of no routine gastric residual volume measurement in mechanically ventilated Infants and children: the GASTRIC Study

Submission date
15/02/2018

Recruitment status
No longer recruiting

Registration date
16/02/2018

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In intensive care units (ICUs) the amount of fluid in a child or baby's stomach (gastric residual volume (GRV)) is regularly measured to help decide if a child is ready to have the feed into their stomach. This fluid is measured by sucking it out via a tube already into the child's stomach. This is a very common practice in ICUs in the UK, but it is unclear if this practice is helpful. Measuring GRV may prevent problems from overfeeding when the bowel cannot cope with milk and is not absorbing feeds. In children, the main problem is vomiting of the stomach contents, and breathing this fluid into the lungs. The main worry in babies under a month old is a very serious infection of the bowel (necrotising enterocolitis). This nursing practice is heavily based on tradition and perceived risk, but benefits have not been proven and it may be harmful as feeds are often stopped, reducing the calories that babies and children receive. Ensuring that babies and children have adequate feed is vital in intensive care, and not doing so slows recovery. It is known that inadequate nutrition is common in babies and children in ICUs and measuring GRV may be contributing to this. It is thought that all children's and baby's ICUs (PICU and NICUs) in the UK measure GRV routinely. Before changing practice in the UK, it is necessary to undertake a study to determine the benefits and safety of not measuring GRV. The aim of this study is to find out whether it is possible to conduct a study of not measuring GRV in UK PICU and NICUs.

Who can participate?
Healthcare professionals working in UK PICU and NICUs who are involved in decision-making around feeding (nurses, doctors and dieticians), and parents of children who have been in a UK PICU or NICU

What does the study involve?
Parents' and healthcare professionals' views around this practice are collected using questionnaires, focus groups and interview. Parents are asked whether this is important to them and whether they would be happy for their child to take part. There is one questionnaire (at 1 month) of existing practice, then a further questionnaire about the best study design at month 4.

What are the possible benefits and risks of participating?
For staff there may be benefits in terms of engagement and involvement in the development of a future study. There are no risks except the time burden of participation.

Where is the study run from?
Liverpool Clinical Trials Research Unit (UK)

When is the study starting and how long is it expected to run for?
April 2018 to September 2019

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Lyvonne Tume
lyvonne.tume@uwe.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Lyvonne Tume

ORCID ID
https://orcid.org/0000-0002-2547-8209

Contact details
Faculty of Health & Applied Sciences
Glenside Campus
Blackberry Hill
Bristol
United Kingdom
BS16 1DD
+44 (0)1173286828
lyvonne.tume@uwe.ac.uk

Additional identifiers

Protocol serial number
HTA 16/94/02

Study information

Scientific Title
A feasibility study of no routine gastric residual volume measurement in mechanically ventilated Infants and children: the GASTRIC Study

Acronym

GASTRIC

Study objectives
To determine if it is possible to conduct a trial of not measuring gastric residual volume (GRV) in UK pediatric and neonatal intensive care units.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Central (Bristol) committee - approval pending

Study design
Mixed methods feasibility study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Critically ill tube fed neonates and children

Interventions
This feasibility study will examine clinician and parent views around a trial of not undertaking this routine intervention of GRV measurement and once trial inclusion/exclusion criteria are agreed then feasibility in terms of number of patients meeting these criteria nationally.

The questionnaires are currently being developed as no existing tools are suitable. There will be one baseline measurement (at 1 month) of existing practice, then a further questionnaire around optimal research design at month 4.

For survey 1 a per-unit response is required (29 PICUs and 192 NICUs) so a 70% unit response rate is anticipated. For survey 2, this will be larger and sent to around 600 PICU staff and 600 NICU staff around the UK. Four focus groups will take place across the UK and around 20-30 parents will be interviewed across the UK.

Intervention Type
Other

Primary outcome(s)
Possibility of conducting a trial of not measuring gastric residual volume (GRV) in UK pediatric and neonatal intensive care units

Key secondary outcome(s))
1. Standard care practices around enteral feeding and GRV measurement assessed using an e-survey in all UK PICUs and NICUs
2. Healthcare professionals (nurses, doctors and dietitians) views around GRV measurement, acceptability of not measuring GRV, alternative methods to assess feed tolerance, willingness to randomise to or comply with a future trial, barriers to recruitment, perceived training needs and

inclusion and exclusion criteria
3. PICU and NICU parents' and/or patients' views around GRV measurement, acceptability of not measuring GRV, willingness to agree to a future trial, barriers to recruitment, patient (parent) centred outcomes and information needs for parents
4. Consensus on future trial issues including optimal trial design, primary and secondary outcome measures and inclusion and exclusion criteria
5. Trial feasibility (in both PICU and NICU) assessed using routinely collected national clinical datasets (PICANet and NNRD) and sample size calculations for a future trial
6. A standard (control) arm (with routine GRV measurement) and an intervention arm (no routine GRV measurement) of a future trial, agreed using a consensus process

The questionnaires are currently being developed as no existing tools are suitable. There will be one baseline measurement (at 1 month) of existing practice, then a further questionnaire around optimal research design at month 4.

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. Healthcare professionals working in UK PICU and NICUs who are involved in decision-making around feeding (nurses, doctors and dieticians)
2. Parents of children who have been in a UK PICU or NICU

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Non PICU or NICU staff or parents who have not had this experience

Date of first enrolment
01/05/2018

Date of final enrolment
01/07/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Clinical Trials Research Unit
Institute of Child Health
Alder Hey Children's Hospital
Eaton Road
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
University Hospitals Bristol

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Data generated from the study will be kept within the Clinical Trials Unit repository and will not be publically shared except within the research team. The qualitative study data will be analysed at the University of Liverpool. All interviews and focus groups will get informed written consent. Surveys will collect unit level data only (survey 1) and expert opinion (survey 2) and consent will be implied by return of the survey.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2020	23/11/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes