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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?
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Study website
www.grvstudy.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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.

Overall study start date
01/04/2018

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

Participant type(s)

Age group
Adult

Sex
Both

Target number of participants
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.

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
England

United Kingdom

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

Sponsor details

Research & Development Department
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8BJ

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Members of the study team are embedded within the UK PICU and NICU community and networks. We will provide ongoing updates during the feasibility study to the PICS-SG, the Neonatal study group meetings (the National Neonatal Network N3, the UK Neonatal Collaborative Network and the Neonatal Clinical Studies Group). Success of the study depends on the engagement of and collaboration with doctors, nurses and dietitians from across the UK PICUs and NICUs. A study Twitter account has been set up @GASTRICStudy to promote awareness of the study and a study webpage at will provide more detailed information about the study both to a parent audience and to a professional audience.

Wider dissemination to the PICU and NICU community will be achieved through presentation at key national (PICS and RCPCH, European (ESPNIC, ESPR, jENS) and International meetings (PICC and COIN) and through publication in high impact journals in the specialities. PICS, ESPNIC, BAPM have multidisciplinary membership and associated academic journals. In accordance with open access policies proposed by the NIHR we will publish the findings of this feasibility study both in a focused PICU (Pediatric Intensive Care Medicine) and NICU (Archives of Diseases in Childhood, Fetal and Neonatal Edition) journal. This will make the results readily accessible to healthcare professionals. The results will also be disseminated through our networks within these communities described above. A final report will also be published in the NIHR HTA journal.

There are a minimum of 4 papers planned as part of this study, the two final study results (one in NICU and one in PICU) will be open access papers submitted for publication by November 2019. Additional documents (such as study protocol, statistical analysis plan, other) will be available within the next 3 months as will the study website.

Intention to publish date
01/11/2019

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