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A Feasibility Study of no routine Gastric residual volume measurement in mechanically ventilated Infants and Children: the GASTRIC Study

Participant Information Sheet for Consensus and Trial Design Meeting

We invite you to take part in a consensus and trial design meeting for the GASTRIC research study

This consensus meeting is part of the GASTRIC Study and therefore you are being invited to take part in a research study. Please ask us if there is anything that is not clear in this information sheet or if you would like more information (contact details overleaf).

The aim of the proposed GASTRIC trial will be to find out whether it is safe and more effective to NOT routinely measure gastric residual volume (GRV) routinely in critically ill babies and children. This GASTRIC feasibility study, is a small research study, which is being done to inform the design of a future GASTRIC trial. Before embarking on a trial, it is important to assess whether it is possible to conduct such a trial. This study aims to gather that information, in terms of finding out about the views about a possible future trial from parents/carers and from healthcare professionals involved in decision-making around enteral nutrition in NICU and PICU.

What is GRV?

GRV is the fluid in a child or baby's stomach. In order to help decide if a child is ready to have the feed into their stomach, GRV is measured by sucking it out via a tube already into the child's stomach. This is a very common practice in intensive care units in the UK, but it is unclear if this practice is helpful.

Why have I been chosen?

You are either a PICU or NICU healthcare professional who is involved in decision-making around enteral nutrition in NICU or PICU (a clinical nurse, doctor or dietician) or a parent/carer of child who has been in the PICU or NICU and already been a part of this study or an expert in research and trial design.

In this consensus and trial design meeting, we aim to share all the data we have gathered, summarise this and get agreement on any outstanding issues or areas of uncertainty. In essence, we want to know your views around a future trial to NOT measure GRV routinely.

What will happen if I take part?

We will ask you to register interest in taking part in this one-day consensus meeting, which will be held at the University of Liverpool venue in London. You will be paid for your travel expenses and catering will be provided on the day. Parents/carers will also be paid for their time to attend this meeting.

This consensus meeting will be led by either Dr Lyvonne Tume (for PICU) or Dr Chris Gale (for NICU) but be facilitated by an independent facilitator to ensure it runs to time. With your permission, we would like to audio-record the day to ensure that we do not miss anything, once this has been transcribed, the audio-file will be deleted.

How will the consensus day run?

We will first summarise all the evidence we have obtained from our feasibility work so far and will present this to you. Then we will ask you about your thoughts about a proposed trial design, outcome measures, standard practice arm of the proposed trial and also the proposed intervention arm (not measuring GRV) of the trial which our French collaborators will present (as they have no measured GRV in their units for many years). The day will be a facilitated discussion about these issues.

What are the possible benefits and risks of taking part?

This qualitative element of this is very low risk. Should you want to discuss any aspect of the study, please contact Lyvonne Tume (details below).

Findings of this study will be used to inform the design of a future larger trial. We cannot promise that you or the families you work with will benefit directly from this study, but many people find that taking part in studies of this sort is useful because they have a chance to air their views and to reflect on things.

Who is involved in this study?

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme is funding the study. Dr Lyvonne Tume (University of the West of England) is the GASTRIC Study Chief Investigator. All information collected about you during this study and any future follow up will be confidential, and will be handled, stored and destroyed in accordance with General Data Protection Regulation (GDPR) and the Data Protection Act (DPA) 2018.

University Hospitals Bristol NHS Foundation Trust is the sponsor for this study based in the United Kingdom; they have delegated the day-to-day management of the study to the Clinical Trials Research Centre (CTRC), which is part of the University of Liverpool. We will be using information from you in order to undertake this study and University Hospitals Bristol NHS Foundation Trust and University of Liverpool CTRC will act as the data controllers for this study. This means that University Hospitals Bristol NHS Foundation Trust and University of Liverpool CTRC are responsible for looking after your information and using it properly. University of Liverpool CTRC will keep identifiable information about you for 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information in the "**How we use your information**" section on the study website here: www.grvstudy.com.

University of Liverpool CTRC will keep your name and contact details confidential and will not pass this information to University Hospitals Bristol NHS Foundation Trust. University of Liverpool CTRC will use the contact details you provided to contact you to confirm attendance at the GASTRIC consensus and trial design meeting, provide you with details about the meeting and confirm any other special arrangements e.g. dietary requirements. University of Liverpool CTRC will destroy your contact details after the consensus and trial design meeting. A copy of the consent form, which will include your name will be collected by the University of Liverpool CTRC to provide confirmation that consent was given. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

University of Liverpool CTRC will keep identifiable information about you from this study for 15 years after the study has finished.

What if there is a problem?

Any complaint about the conduct of this study, the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, then please speak to the researchers who will do their best to answer your questions (see contact details below). If you remain unhappy and wish to complain formally, then you can do this via the study Sponsor:

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How to contact us

If you have any questions, please contact:

Study Chief Investigator:

Dr Lyvonne Tume
Email Lyvonne.tume@uwe.ac.uk
Telephone 0117 32 86828

Or alternatively, please contact the GASTRIC study team at University of Liverpool, CTRC:

GASTRIC Study Coordinator
Email gastric.study@liverpool.ac.uk
Telephone 0151 794 9838

Thank you for your time.
We are very grateful that you are considering taking part in this study.

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