



The GASTRIC Study

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Parent/ Carer Information Sheet

We invite you to take part in research study

- Children in intensive care often struggle to get even half of the amount of calories they need. Having enough calories is important when a child is sick to ensure they have enough energy for breathing and healing.
- There are many reasons why children do not get enough calories, but one routine practice that may be contributing to this, is the regular measuring of the child's stomach contents. This can lead to stopping the child's feeds if staff are concerned about the amount or colour of the stomach contents.
- This clinical trial is designed to find out whether NOT routinely measuring the child's stomach contents during feeding is safe and beneficial.
- Before you decide if you want to give your permission for your child to be included in this trial, it is important for you to understand why the research is being done and what it will involve.
- Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish.
- Please ask the nurse or doctor who has spoken to you about the GASTRIC Study if there is anything that is not clear or if you would like more information.

Important information you need to know

- Your child is currently being fed by a tube in intensive care.
- Across the UK, children that are being tube fed in hospitals have the amount of fluid in their stomachs measured through a tube placed into their stomach. This is called the gastric residual volume or GRV.
- The amount of fluid in their stomach acts as a 'guide' for when to start, stop and how quickly to increase the amount being fed to the child.
- While it is a standard part of the tube feeding process, it is not an accurate measurement and may lead to a child having less calories than they could have digested.
- Possible risks of NOT measuring GRV: we may not know if the child's stomach is becoming full, which may cause them to vomit. However, there are other ways we can tell if the stomach is becoming full such as looking at how big their stomach area (abdomen) is or seeing if they are in any discomfort.
- Possible benefits of NOT measuring GRV: your child may receive more calories, giving them more energy for healing and breathing.
- We do not know whether it is better to measure or not measure GRV.

More detailed information about the GASTRIC Study

Why are we doing this study?

Most children in intensive care cannot eat normally by mouth and require feeding into their stomach via a tube (a naso-gastric tube).

It is important that we provide enough calories to children through their feeds while they are sick, as this can help them to get off the breathing machine 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 so often for various reasons, one of which is that the amount of fluid in the stomach is 'high', which makes the child at risk of vomiting.

Across the UK, it is a common practice in all Paediatric Intensive Care Units (PICU) for nurses to check stomach contents by attaching a syringe to the end of the feeding tube and gently sucking out the child's stomach contents 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 or referred to as an 'aspirate'.

If a child has a 'large' GRV's then 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 drugs we use slow down the stomach's actions. The measurement of this (GRV) through the naso-gastric tube is known to be quite inaccurate. Several things can affect how much GRV the nurses gets back, including the size and type of the tube, the size of syringe they use to pull back with, your child's position and the position of the end of the tube in your child's stomach. Therefore, a decision may be taken to stop feeds when there is no need to.

We do not know whether it is better to measure GRV routinely or not.

We expect to enrol children in PICUs across the UK in this study over 3 years.

Why has my child been chosen?

Your child is in intensive care and requires feeding via a tube into their stomach (a naso-gastric tube).

What will happen if I allow my child to be in this study?

If you decide to allow your child in this study, they will be allocated at random to receive either usual care (regular measurement of GRV every 4-6 hours) or no routine GRV measurement.

If they are randomised to receive no GRV measurement, they will be fed as per the usual guidelines but GRV will not be measured and so feeds will not be stopped based on this value.

Whichever group they are part of, your child's feeding will be assessed and monitored in other ways to ensure their safety. For example, we will look at your child's stomach for any signs of swelling, see if they are in any pain or discomfort and check their nappy to see how often they pass a stool. If your child starts to vomit or shows other signs of feed intolerance, they will be assessed and their feeds will be reviewed.

They will still have a very small amount of this fluid taken out to see how acidic the fluid is (called a PH test) and ensure that the tube is in the correct position. This is not the same as measuring GRV where the whole of the child's stomach contents is pulled out.

Your child will be in the study for the time they are in intensive care and on the breathing machine and being tube fed.

Are there any risks or benefits to being in this study?

Small studies have not found any additional risks in children who did not have their GRV measured regularly, and in some countries (France) it is not routinely measured.

The risk associated with not measuring GRV 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 and children in intensive care often vomit anyway while receiving tube feedings even when we do measure the GRV regularly. As the return of the fluid (back into the child's stomach) may cause vomiting.

If your child is selected to having their GRV measured they will be receiving standard UK care

While we cannot guarantee taking part in this study will benefit your child, they may receive more of their required calorie (energy) needs from their feeds and this is important for recovery and length of illness. Also by being in this study there will be a more detailed observation of your child's calorie and feed intake, along with other things such as the time they spend on the breathing machine

Do I have to allow my child to take part and can I change my mind?

It is entirely up to you whether you allow your child to be in the study. If you do agree to allow your child to be on the study, and at any point, you wish to withdraw them from the study; you are completely free to do so at any time, without giving a reason. This will not in any way affect the care that either you or your child receives.

What happens when this research stops?

After your child has been discharged from intensive care or is taking food normally (not via the feeding tube unless this is normal for them) the study will stop and your child will receive the usual care as they normally would be during feeding.

What happens when this research stops?

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme is funding the study. The study has been reviewed by the NIHR HTS and the (<INSERT NAME>) Research Ethics Committee (<insert REC NUMBER>), who have agreed that the study is being conducted in a correct and appropriate manner. Dr Lyvonne Tume (University of xxxxxxxxxxxxxxxxx) is the GASTRIC Study Chief Investigator. The GASTRIC research team are qualified to do this study because they have all the specialties and skills needed. Members of team have a lot of experience in caring for children with intensive care and are very active in health research. Parents of children who have experienced being in intensive care have been involved in the development of this study.

What will happen to the results of this study?

This study will be presented at conferences and written up for publication in an academic journal but your child will not be identifiable. Will we prepare a summary of the study results for parents who would like a copy, as well as being made available on the study website and via the twitter feed. We hope that this study will tell us whether not measuring GRV is safe, and increases the amount of feed that children in intensive care receive.

Will my child's taking part be kept confidential?

XXXXXXXXXXXXXXXXX is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means we are responsible for looking after your information and using it properly.

xxxxxxxxxxxxxxxxx will keep identifiable information about you for 10 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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identification information possible.

You can find out more about how we use your information; InformationGovernance@UHBristol.nhs.uk

Your child's study information will be kept completely confidential and stored only on a very secure password protected computer in the trials unit. Only the study team involved in this study will be able to look this information.

What if there is a problem?

Complaints: XXXXXXXXXXXXXXXXXXXX NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that University Hospitals Bristol NHS Trust is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator. The normal National Health Service complaints mechanisms are also available to you.

For NHS service advice or support please contact: Patient Advice and Liaison Services (PALS) services. Go to <http://www.nhs.uk/> to find your local PALS contact details. For support on any other issue please contact: The Samaritans. Website: <http://www.samaritans.org> telephone: 116 123.

Glossary of terms?

- Naso-gastric tube (NG tube): A small tube passed from your child's nose (or sometimes the mouth) into their stomach to allow feeding
- GRV: Gastric Residual Volume the amount of fluid pulled back (aspirated with a syringe by the nurse) from the child's NG tube, reflecting the amount of fluid in the child's stomach.
- Aspirate: The same as the GRV, the aspirate the fluid itself we get from the child's stomach.
- pH: how acid or alkaline a fluid is, tested on special paper – measuring this tells us where the end of the NG tube is, because the stomach fluid should be acid.