neoGASTRIC

Parent Information Sheet

The neoGASTRIC study is for babies born more than 6 weeks early and needing a feeding tube

Key information to know about the study:

- **All babies will be in the study unless you let a member of the neonatal team know that you do not wish your baby to take part**
- We are comparing two ways of caring for babies having tube feeds, both ways are part of routine care and both are commonly used in neonatal units across the UK
- We do not believe there are any additional risks of taking part
- Your baby will be enrolled into the study within 24 hours of them starting feeds
- We will collect information about your baby and their feeds
- This study is being run in more than 30 hospitals in the UK and Australia for about 3 to 4 years
- 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

The neoGASTRIC study: Avoiding routine gastric residual volume measurements in neonatal critical care

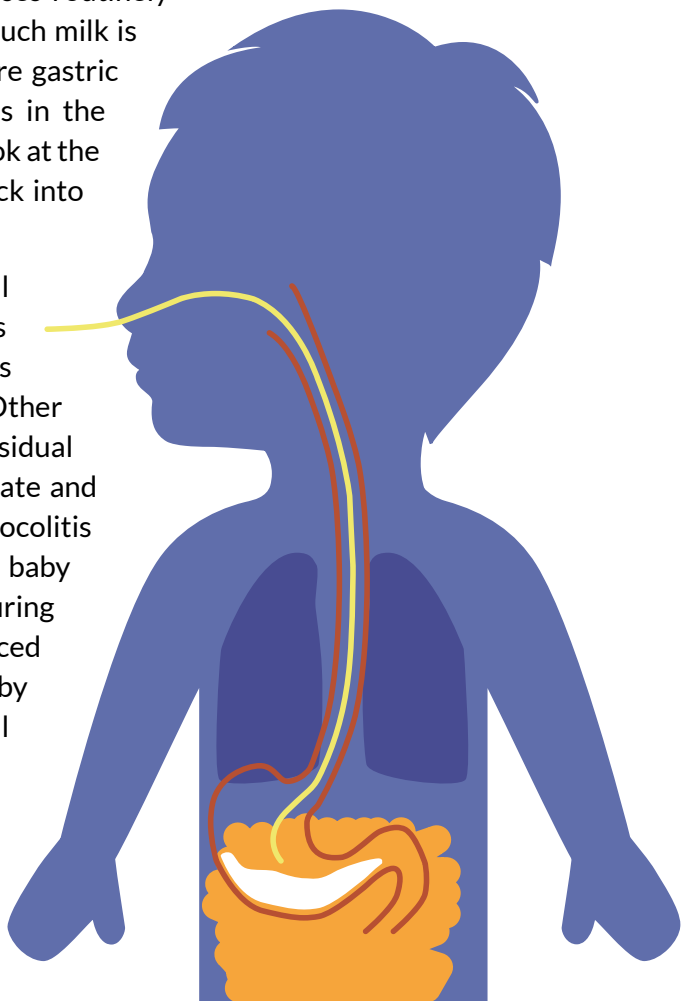
IMPERIAL

This neonatal unit is taking part in an important research study called neoGASTRIC which is comparing care practices that already take place in neonatal units across the United Kingdom (UK). We plan to include every eligible baby in the study unless you tell us you do not want your baby to take part (opt out).

What is the purpose of this study?

Premature babies aren't always able to suck and swallow their milk. That's why they are fed milk every few hours through a soft tube which lies in their stomach. The tube is called a 'gastric tube' and is placed via the nose or mouth. Some babies can't tolerate lots of milk soon after birth, so the amount of milk given at each feed is increased slowly while they also receive fluid or nutrition into the vein (intravenously).

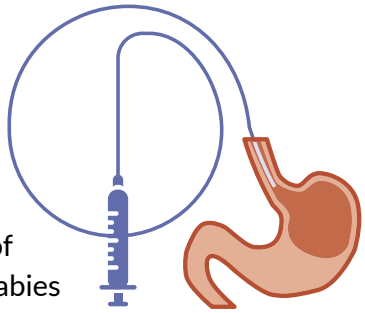
When a baby has a gastric tube in, some doctors and nurses routinely measure gastric residual volumes – checking to see how much milk is left in the baby's stomach before the next feed. To measure gastric residual volume, a syringe is used to gently suck what is in the stomach up through the gastric tube. Nurses and doctors look at the amount and appearance of this, then they may put this back into the baby's stomach again.



Some doctors and nurses routinely measure gastric residual volumes because they think it might help tell if the baby is coping with their feeds, and may help identify signs of a serious but rare gut disease called necrotising enterocolitis (NEC). Other doctors and nurses think that routinely measuring gastric residual volumes may not be a good idea because it can be inaccurate and we do not know if it does help to identify necrotising enterocolitis (NEC). It also increases the amount of procedures each baby has, and may be uncomfortable for them. Routinely measuring gastric residual volumes may also lead to feeds being reduced or even stopped, this will delay the time it takes for the baby to reach full feeds and might affect how well they grow. It will also mean a baby will need intravenous nutrition for longer which can lead to potential problems like infections.

In the UK about half of doctors and nurses routinely measure gastric residual volumes and about half don't – so both approaches are standard treatment.

Why are we doing this study?



Some small studies suggest that it might be better to not routinely measure gastric residual volumes. However these small studies were not able to test whether not routinely measuring gastric residual volumes makes detecting necrotising enterocolitis (NEC) harder. So to check whether not routinely measuring gastric residual volumes is safe or harmful we need to collect information on thousands of premature babies. The neoGASTRIC study will answer this question by comparing babies who do not have routine gastric measurements with those who do to see if they can reach full feeds quicker without increasing their chance of getting necrotising enterocolitis (NEC). It is important to know that large gastric volumes do not always mean a baby has necrotising enterocolitis (NEC). We are doing this study because routinely measuring gastric residual volumes may not be the best way of knowing a baby is at risk of necrotising enterocolitis (NEC). Doctors and nurses will still closely monitor your baby for signs of necrotising enterocolitis (NEC) by checking them regularly and looking at their heart rate and other signs.

Why has my baby been chosen?

We are including all babies born 6 or more weeks early (before 34 weeks of pregnancy) who require tube feeding, unless there is another medical reason why they should not take part. We hope to include over 7000 babies overall in the study (UK and Australia combined).

Does my baby have to take part?

No, neoGASTRIC is an opt-out study. This means that all babies will take part unless you let a member of the neonatal team know that you **do not** wish your baby to participate.

What do I do if I don't want my baby to take part?

If you don't want your baby to take part in neoGASTRIC, please inform a member of the neonatal team. Your baby will continue to receive the routine care of that unit.

What will happen if I do want my baby to take part?

You don't need to do anything. All babies taking part will be randomly allocated to either routine gastric residual volume measurements, or no routine gastric residual volume measurements. This will be decided by chance: babies will have an equal chance of being in either group.

If your baby takes part in neoGASTRIC we will ask the team looking after your baby to do one of two things: either to routinely measure gastric residual volumes every few hours, or to not do this. All other day-to-day decisions around feeding and care will be made by the doctors and nurses looking after your baby.

Whichever group your baby is in the position of their gastric tube will always be checked by sucking up a tiny amount of milk prior to feeding to confirm tube position.

Babies taking part in neoGASTRIC will not have any additional tests and your baby will be looked after in the same way as any premature baby not taking part in the study.

There will be no payment or reimbursement of expenses for taking part.

It is very unlikely that anything unexpected about your baby will be found in the study because there are no additional tests being done in the study. If anything unexpected is found we will immediately tell the clinical team looking after your baby.

Can I change my mind?

Yes – whatever you decide, your baby's care will not be affected. If you opt out of the study we unfortunately won't be able to re-enter them at a later time. If you change your mind after your baby is enrolled in neoGASTRIC and no longer wish your baby to participate, the decision about whether to routinely measure gastric residual volumes will revert to the clinical team. We will ask if you are happy for us to continue to collect data about your baby. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.

If you choose to stop taking part in the study, we would like to continue collecting information about your baby's health from central NHS records. If you do not want this to happen, tell us and we will stop. This will not affect any healthcare or support your baby may be receiving separately.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

What are the possible benefits and risks of taking part?

Both approaches in neoGASTRIC are currently routinely practised in the UK and Australia so we do not believe there are any additional risks or benefits of taking part in neoGASTRIC. Not routinely measuring gastric residual volumes might lead to babies reaching full feeds quicker which might reduce the risk of infections – but we will only know this after we finish the neoGASTRIC study. We do not think there will be a greater risk of necrotising enterocolitis (NEC) from not routinely measuring gastric residual volumes because countries which do not routinely do this, such as France, have similar amounts of necrotising enterocolitis to the UK. Doctors and nurses will continue to look for necrotising enterocolitis (NEC) through regular checks of your baby and closely watching their heart rate and other signs.

How long will my baby be in the study?

Unless you opt out, your baby will be enrolled into the study within 24 hours of them starting tube feeds. We will continue to collect information about your baby – such as if they get an infection or necrotising enterocolitis (NEC) until they reach 4 weeks after their expected due date or they are discharged home.

What if relevant new information becomes available?

The neoGASTRIC website will be updated if any information becomes available during the study that might make you change your mind about your baby's involvement.

What happens when the research study stops?

At the end of the study, the decision about whether to routinely measure gastric residual volumes will revert to the clinical team.

How will we use information about your baby?

We will need to use information from your baby's medical records for this research project. This information will include your name, your address, your age and ethnicity, your baby's name and your baby's NHS number and date of birth. We will also link to routinely collected national records held for your baby to track your baby's progress in the future. These databases include the National Neonatal Research Database, Hospital Episode Statistics and National Pupil Database. You can opt-out of this data linkage by contacting a member of the trial team.

People within Imperial College London and their study team will use this information to do the research or to check your records to make sure that the research is being done properly and the information held (such as contact details) is accurate.

We will keep all information about you safe and secure. This information will be sent to the Study Coordinating Centre at the University of Oxford, National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU). Only the research team, the study organisers in Oxford and people from the sponsor or regulatory authorities (who check on studies like this) will see your data. The coordinating centre in Oxford will keep identifiable information from this study for 25 years after the study has finished.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

For more information on how we process and protect your baby's data, please see our website: ***www.npeu.ox.ac.uk/neogastric***.

Further information can also be found at the NHS Health Research Authority's website:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

Imperial College London is the sponsor for this study and will act as Joint Data Controller with the University of Oxford for the purposes of this project. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for 25 years after the study has completed in relation to primary research data. The study is expected to finish in October 2026.

For more information / confirmation regarding the end date please contact the study team, see '**Where can you find out more about how your information is used**' for contact information.

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

> Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the ***UK Policy Framework for Health and Social Care Research***.

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), both organisations rely on "scientific or historical research purposes or statistical purposes.

International transfers

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

Other Imperial College London employees include staff involved directly with the research study or as part of certain secondary activities (which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

Potential use of study data for future research

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at ***www.hra.nhs.uk/information-about-patients/***
- by asking one of the research team
- by sending an email to ***neogastric@npeu.ox.ac.uk***
- by ringing us on ***(0)1865 617927***
- or by going to ***www.npeu.ox.ac.uk/neogastric***

Who is organising and funding the research?

The National Perinatal Epidemiology Unit, Clinical Trials Unit (NPEU CTU) at the University of Oxford, UK in partnership with Monash University, Australia are coordinating and managing the study on behalf of the sponsor, Imperial College London. The study is funded by the National Institute for Health and Care Research in the UK and National Health and Medical Research Council in Australia. The doctors and nurses conducting the research are not receiving payment or benefits over and above their normal salary.

What will happen to the results of the research study?

Full details of the trial will be made available through the trial website: ***www.npeu.ox.ac.uk/neogastric***. It will also be disseminated through conference presentations, via charities such and Bliss and SSNAP as well as a report being sent to the funders.

Who is the study team and how can I get in touch?

We are medical professionals taking care of newborn babies and undertaking research to improve neonatal care. Please see the contact details below to get in touch.

Who has reviewed the study?

All research in the NHS is assessed by an independent group of people to protect the interests of participants. This study has been reviewed by the London-Riverside Research Ethics Committee.

How will I find out the results of the study?

Once the study is complete the data will be analysed and published in a medical journal. The results will also be available on the trial website. Neither you nor your baby will be identified in any report or publication about the study.

What happens if I have a complaint?

If you wish to raise a complaint about how we have handled your personal data, please contact the research team (contact details below)

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College 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 (see details below). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

Contact for further information or if you have any concerns:

Chief Investigator:

Professor Chris Gale
Imperial College London
0203 315 3519
christopher.gale@imperial.ac.uk

Principal Investigator:

{_PI_}

{_PALS NAME_}:

{_PALS_}

Lead Research Nurse:

{_MIDWIVES_}

Thank you for reading this leaflet – please discuss this study with the doctor or nurse who is looking after your baby if you have any questions.

For more information scan here

neoGASTRIC Study Team

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FUNDED BY
NIHR | National Institute for Health and Care Research

NHMRC-NIHR Collaborative Research Grant Scheme. The views expressed are those of the author(s) and not necessarily those of the NIHR, NHMRC or the Department of Health and Social Care.