BASE

Bicarbonate for AcidosiS in very pretErm babies

Parent Information Leaflet

This study is for premature babies who have metabolic acidosis

Please read this leaflet to find out more.

watch our video here

If you would like further information, please ask a doctor or nurse caring for your baby.

Funded by NIHR | National Institute for Health and Care Research

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The BASE study: Key Information

This information leaflet provides information about the BASE Study

- You have been given this information leaflet because your baby has been born prematurely.
- The BASE study is looking at whether or not to routinely give sodium bicarbonate when a baby has a condition called metabolic acidosis.
- Metabolic acidosis is a build-up of acid in the blood that often occurs in premature babies.
- Babies will be put into one of two groups, to be routinely given sodium bicarbonate or not when they have metabolic acidosis. Which group they are in will be decided at random by a computer program.
- No matter which treatment group your baby is in, if there is a clinical need to either stop or start giving sodium bicarbonate to your baby, your baby's clinical team will do so.
- We will collect information from your baby's health record to complete the study.

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Bicarbonate for AcidosiS in very pretErm babies

What is the BASE study?

The BASE study is for premature babies born more than 9 weeks early. The study is looking at whether or not to routinely give a drug called sodium bicarbonate when a baby has a condition called metabolic acidosis, which means there is a build-up of acid in the blood. Many babies that are born very prematurely will experience metabolic acidosis during their hospital stay.

Some doctors believe that sodium bicarbonate lowers acid levels in the blood and helps the working of the heart, but others believe it can raise acid levels inside the cells of the body which can affect blood flow to the brain and other organs in the body. Both giving and not giving sodium bicarbonate when a baby has metabolic acidosis are current practice and your baby could be treated either way whether they are in the study or not. The reason practice differs widely is because the use of sodium bicarbonate to treat metabolic acidosis in preterm babies has never been properly studied.

What is the study trying to find out?

We want to find out if giving sodium bicarbonate impacts the health of premature babies, to help improve the care they receive in the future.

By doing this study, it will also help us understand whether doctors and nurses can collect the information needed and provide care as planned, and whether future research in this area is possible.

Does my baby have to take part?

It's up to you to decide whether or not your baby takes part. If you decide you do not wish your baby to take part, you do not have to give a reason and your baby's care will not be affected in any way. If your baby takes part and you then change your mind about this later, you are free to withdraw them at any time. We will only collect and use data from the baby's hospital records relating to events occurring up to the time of withdrawal.

What will happen if my baby is in the BASE study?

If you tell us that you would like your baby to take part your baby will be included in the BASE study if and when they develop metabolic acidosis. All babies taking part will be put into one of two groups. Half the babies in the study will be given sodium

bicarbonate when they have metabolic acidosis and half will not. Other than this, all aspects of their care will be exactly the same as routine care, including treating any known causes of metabolic acidosis.

There will be an equal chance of being in either group. Your baby's group will be chosen randomly by a computer program.

The 'Sodium Bicarbonate' Group

Babies in this group will be given a dose of sodium bicarbonate into a vein via a catheter (cannula). The amount they are given and how long they receive it for will be decided by their doctor.

The 'No Sodium Bicarbonate' Group

Babies in this group will not routinely receive sodium bicarbonate if they develop metabolic acidosis.

No matter which treatment group your baby is in, if there is a clinical need to either stop or start giving sodium bicarbonate to your baby, your baby's clinical team will do so.

QuinteT Study

You may also be approached to take part in a study led by the University of Bristol's QuinteT research group which explores parents' views about taking part in research. The aim of the QuinteT study is to improve our understanding of parents' experiences of having been invited to consider participation in the BASE study.

Taking part in this study is optional, and it won't affect whether your baby can take part in the BASE study. Details about this study are covered in a separate information leaflet.

Are there any possible disadvantages or risks from taking part?

Both using and not using sodium bicarbonate for metabolic acidosis are current practice in the UK, so there are no additional risks to being involved in the study. Most babies who develop metabolic acidosis are likely to have a cannula as part of routine care, however, occasionally, a baby may not already have one in place, in which case their doctor will place one in order to give sodium bicarbonate. This is also what happens in routine clinical practice. Placing cannulas is a minor routine medical procedure. There can be some low level risks of bleeding, bruising or infection at the insertion site.

What are the possible benefits of taking part?

Whilst there are no direct benefits to taking part in the research, your contribution will help to improve the future care for premature babies, like your own.

Will I be reimbursed for taking part?

There is no payment for taking part in the study.

What will happen to the results of this study?

At the end of the study, we will send you a copy of the results and they will also be available on the study website. We will also share the results at conferences. Data from this study may be shared with other groups who are carrying out similar work in the future. Your baby's details will not be identified in any publication or data shared.

You and your data

How will you collect data?

We will collect most of the routine data we need for the study directly through your baby's hospital record, using your baby's healthcare number. Whilst your baby is in hospital we will also record additional information about any episodes of metabolic acidosis your baby develops and how they are treated. We will also collect a small amount of data about the mother, through your baby's hospital record.

If you agree for your baby to take part, we will collect information to check if your baby meets the criteria to be included in the BASE study and reasons why they may not have been included if they did meet the criteria.

Keeping your data safe

All information collected about you and your baby during the study will be kept strictly confidential and stored securely.

What will happen to my baby's data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from your baby's hospital records for this research project. We will share your information related to this research project with the following types of organisations: National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) at the University of Oxford (Sponsor) and Imperial College London.

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

This information will include your baby's name, healthcare number, sex and date of birth. We will also collect contact details (name, address and email address) for both parents.

People will use this information to do the research or to check your records to make sure that the research is being done properly. Responsible members of the University of Oxford, and regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

We will keep all information about you safe and secure by:

- Storing all electronic data in a secure place
- Restricting access to only those people who need it for the research, using individual logins and passwords
- Backing up data everyday
- Not storing data on individuals' computers

Your personal data will not be shared outside the UK.

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.

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your data for a minimum of 25 years in line with Clinical Trials Regulations as required. Once the retention period has finished, the study data will be kept in a way that does not identify you.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we may keep information about you that we have already collected. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

You can find out more about how we use your information by:

- Asking one of the research team (see contact details at the end)
- Sending an email to ***base@npeu.ox.ac.uk***
- Calling the BASE study team on 01865 289716
- Contacting the University's Data Protection Officer ***data.protection@admin.ox.ac.uk***
- Looking at the University's privacy notice available at: ***compliance.admin.ox.ac.uk/research-data***

The Study Coordinating Centre in Oxford will keep identifiable information about you and your baby from this study for 25 years after the study has finished. For more information on how we process and protect you and your baby's data, please see our website:

www.npeu.ox.ac.uk/ctu/privacy-notice

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at:

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/

Further Information

Who can I contact if I have a complaint?

In the first instance please talk to the clinical team looking after your baby. If you wish to complain about any aspect of the way that you or your baby have been treated you may use the normal National Health Service complaints procedures and the Patient Advice and Liaison Service (PALS) at your hospital will advise you about this.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact the Chief Investigator Sabita Uthaya or you may contact the Research Governance, Ethics and Assurance (RGEA) office at the University of Oxford or the head of RGEA, by emailing ***RGEA.Complaints@admin.ox.ac.uk***.

You can find all relevant contact details on the back page of this leaflet.

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment provided.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team, their contact details are on the back page.

Who is organising and funding the study?

The study is funded by the National Institute for Health and Care Research (NIHR151086) which is the research arm of the NHS. The study is sponsored by the University of Oxford and is being run by the National Perinatal Epidemiology Unit Clinical Trials Unit at the University of Oxford. The Chief Investigator, Dr Sabita Uthaya, is employed by Imperial College Hospital, London.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests and make sure it is done to the highest standards. This trial has been reviewed and given favourable opinion by Nottingham 2 Research Ethics Committee, reference: 23/EM/0244. If you would like more information, please ask a doctor or nurse caring for your baby.

Contact Information

Chief Investigator Dr Sabita Uthaya, Imperial College London (s.uthaya@imperial.ac.uk)

The BASE study team (base@npeu.ox.ac.uk)

Thank you for reading this information.

Local contacts

Principal Investigator

{_PI_}

Local Research Nurse

{_C2_}

{_C3_}

{_PALS Name_}

{_PALS_}

Contact address:

The BASE Study Team

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