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.

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NIHR | National Institute for Health and Care Research

Imperial College London

NPEU Clinical Trials Unit

OXFORD POPULATION HEALTH NPEU

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.
- 3,764 babies are expected to take part, from hospitals across the UK.
- 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.
- When your baby reaches around two years of age, you will be asked to complete a questionnaire, letting us know about your child's development. This is the only questionnaire you will be asked to complete.
- We will collect information from your baby's health record and contact details for you (and your partner) to enable us to complete the study.

BASE

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 short and long-term health of preterm babies, to help improve medical practice and treatment in the future.

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.

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. But when we send you the questionnaire when your baby is 2 years old we will send you a £15 high street voucher to compensate you for your time.

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.

When your child is around 2 years old, we will ask you to complete a questionnaire about their development. This will be sent to you by email, text message, or post. This is a standard questionnaire that is often used routinely in neonatal follow up clinics for these children.

Keeping your data safe

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

The research team at the National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) at the University of Oxford and at Imperial College London will have access to your data. Responsible members of the University of Oxford and [the relevant NHS Trust(s)] and regulatory bodies may also be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What personal information will you collect about me and my baby?

We will collect some personal information about your baby including name, healthcare number, sex, and date of birth. We will also collect contact details (name, address, email address and telephone number) for both parents. This information will be sent to the Study Coordinating Centre at the University of Oxford, NPEU CTU.

Where else may my data be shared?

Personal identifiable information listed above for your baby may also be shared with national databases managed by NHS England (or an equivalent national database) to get up to date contact information before your child's first and second birthday. This is data that is already held on these national databases.

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. Data protection regulation requires that we 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 and the data controller and is responsible for looking after your information and using it properly.

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

Further information about how personal information is used can also be found at the NHS Health Research Authority's website:

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.

For study conduct related complaints, contact the Chief Investigator Sabita Uthaya or you may contact the Research Governance, Ethics and Assurance (RGEA) office at the University of Oxford on 01865 616480, 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 University of Oxford, as Sponsor, has appropriate insurance in place so that, in the unlikely event that you suffer any harm as a direct consequence of your participation in this study, you can claim compensation without having to prove that University of Oxford is at fault. Your legal rights to seek compensation will not be affected. NHS indemnity also applies in respect to any clinical treatment provided.

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

<insert name>

<Insert contact details>

Local Research Nurse

<insert name>

<Insert contact details>

{_PALS Name_}

<Insert contact details>

Contact address:

The BASE Study Team

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