BASE
Bicarbonate for AcidosiS in very pretErm babies

BASE Observational Study
Parent Information Leaflet

Key information

- Our neonatal unit is participating in a study that involves collecting some health information about babies born more than 9 weeks early.
- All babies born more than 9 weeks early will be included in this study **unless** you let us know that you **do not** want your baby to take part.
- **Taking part will not change your baby's care in any way.** There will be no extra treatments or interventions.
- We will collect information from your baby's medical record to complete the study.

This study is looking at a condition called metabolic acidosis in premature babies. We want to understand how often this condition occurs, how doctors treat it and how the condition and treatment affect the health of premature babies.

There are no disadvantages or risks of taking part. Information from this study will help to improve the future care of premature babies like yours.

What is Metabolic Acidosis?

Metabolic acidosis is a build-up of acid in the blood. Many babies that are born very prematurely will experience metabolic acidosis during their hospital stay. Your baby may or may not experience it.

What information will be collected?

We will collect information from your baby's medical record for this study, including details about episodes of metabolic acidosis (if they occur) and how they were treated. We will record your baby's healthcare number, sex, date of birth and postcode. We will also collect some information about the mother, through your baby's medical record.

Does my baby have to take part?

This is an **opt-out study**. This means that all babies will be entered in the study unless you let a member of the neonatal team know that you **do not** wish for your baby to be involved.

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 relating to events occurring up to the time of withdrawing.

What will happen to the results of the study?

At the end of the study, the results will be available on the study website (www.npeu.ox.ac.uk/base). 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 will not be identified in any publication or data shared.

Will my taking part in the study be kept confidential?

Information about you and your baby will be sent to the Study Coordinating Centre at the University of Oxford, NPEU CTU. All information collected about you and your baby during the study will be kept strictly confidential and stored securely.

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*.

What if there is a problem?

If you have a concern about any aspect of this study, please speak with the clinical team looking after your baby.

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 Chief Investigator Sabita Uthaya or University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk

You can find all relevant contact details at the end of this leaflet.

The University of Oxford, as the study sponsor, has appropriate insurance in place to cover this study.

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 NPEU CTU at the University of Oxford. The Chief Investigator, Sabita Uthaya, is employed by Imperial College Hospital.

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 study has been reviewed and given favourable opinion by [name and reference number] Research Ethics Committee.

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

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 healthcare number, sex, date of birth and postcode.

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 [the relevant NHS Trust(s)] and regulatory bodies 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*

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/*.

Contact Information

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

If you have any questions please ask a member of the neonatal team, or you can contact the BASE study team at *base@npeu.ox.ac.uk*.

Scan the QR code to view the BASE Study website or visit *www.npeu.ox.ac.uk/base*

Thank you for reading this information.

Principal Investigator

{_PI_}

Local Research Nurse

{_C2_}

{_C3_}

Contact details

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