

Participant Information Sheet

NeoBath Study: Bathing babies in Neonatal Care

IRAS ID: 329394

University College London are inviting your baby to take part in a study called the NeoBath study: developing a study to find out how often we should bath babies in neonatal care to prevent infection

- Please take time to read the following information carefully. Before you decide we would like you to understand why the research is being done and what this involves for you and your baby.
- One of our team will go through the information sheet with you and answer any questions you have.
- Talk to friends and relatives if you wish.
- If you choose not to take part, this will not affect the care your baby receives in any way.

Part 1 – *What is involved in this feasibility research study?* Tells you the purpose of the study and what will happen if your baby takes part.

Part 2 – *Supporting information* gives you more detailed information about the conduct of the study

- Ask us if anything is not clear, or if you would like more information.

Important things that you need to know

- Preterm or unwell babies on neonatal units are at higher risk of infection, as they may have thin skin or procedures that unfortunately damage their skin as part of their care
- Bathing babies could help prevent infection by removing harmful skin bacteria, however we do not know how often to bath babies for this to make a difference

- We are inviting babies who were born at UCLH at 30 weeks of gestation or above, who weigh more than 1kg, and who have healthy skin
- Feasibility studies test a study on a small scale (one neonatal unit), to determine the best way to carry the study out in a larger trial (several neonatal units)
- The study will take part next to your baby's cot in the neonatal unit
- Your baby will be allocated to receive a bath every 4 or every 7 days
- A cotton-wool bud type swab will gently be brushed on your baby's underarm and groin to collect a small amount of skin cells, before and after their bath
- We will compare the bacteria collected by the skin swabs before and after the bath, to see what affect the bath has
- We will ask your feedback about the study
- Results will be used to create a larger study to explore whether bathing babies more frequently can reduce their risk of infection

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If you have any questions about this study, please talk to the study team: Dr Katie Gallagher (katie.gallagher13@nhs.uk)

Part 1 – What is involved in this feasibility research study?

1. Why are we doing this study?

Human skin is naturally covered in helpful germs that help protect us from harmful ones which can cause infections. But babies who are born early or unwell and need special hospital care in a neonatal unit often have very delicate skin, or may need medical procedures that can damage their skin. This can reduce the number of helpful germs and make them more likely to get infections.

Bathing babies in neonatal units can help clean their skin and remove harmful germs. Bathing babies too often, however, might wash away the good germs too, which could increase their risk of infection. Right now, we don't know how often babies in neonatal care should be bathed to get the balance right, and neonatal units across the country are doing things differently. Bathing babies is also an important way for parents to bond with their baby and build confidence before discharge home.

The study will help us to find out the best way to test how often babies in neonatal care should be bathed, to reduce their risk of infection. We want to understand what parts of the study work well and what could be improved, especially from the parents point of view. If this step goes well, we can do a bigger study to look at whether bathing affects how often babies in neonatal units get infections.

What does the study involve?

The study will help us find out how often it's best to bath babies in neonatal care – either once or twice a week. The study will include 50 babies in total. Half will be bathed every 4 days, the other half every 7 days. Your baby will be randomly placed into one of these two groups. If your baby is in the 4-day group, they will have 6 baths in total. If your baby is in the 7-day group, they will have 4 baths in total. Your baby will be in the study for up to 28 days, or until they go home – whichever comes first.

To understand how bathing affects the tiny germs (microorganisms) that live on the skin, we'll gently take two small skin swabs. The swab is like a soft cotton bud, and we'll use it to lightly wipe the skin near your baby's underarm and groin. We will take one swab just before the bath and one about 30 minutes after. These swabs will be checked to see how the skin germs change after a bath and whether this affects infection risk.

Baths will happen next to your baby's cot in the neonatal unit. A research nurse or your baby's regular nurse will always be there to support you. We use a special, gentle method of bathing babies called "swaddled bathing." This involves your baby being wrapped in a soft cloth or blanket and placed in a warm baby bath (up to their shoulders). One arm or leg will be unwrapped, gently washed, and rewrapped, so your baby stays warm and comfortable throughout. We'll check your baby's vital signs (heart rate, breathing, and temperature) during the time of the bath to make sure they are doing well.

We would like to hear from some parents about their experiences of taking part in the study. If you'd like to share your thoughts, you can tick the box on the consent form. Some parents will be invited to have a short interview (around 30 minutes) with the research nurse. To ensure that we capture what you would like to tell us correctly, we will record the interview using MS Teams, with your consent. This will help us to improve the study for the future. If you don't hear from us, it just means we've spoken to the number of parents we needed — and we still really appreciate your interest.

The interview is completely optional. You can still take part in the bathing study even if you don't want to give feedback.

2. Why has my baby been asked to take part?

Your baby has been invited to take part because they:

- a) were born at UCLH
- b) are over 30 weeks of gestational age
- c) weigh more than 1kg
- d) are clinically stable (they do not require the help of a breathing machine to support their breathing, or medicine to support their blood pressure)
- e) have healthy skin and do not have any cannulas present for any medicines

3. Do I have to take part?

It is up to you to decide to join the study. We will explain the study to you and go through this information sheet together. If you decide to take part, we'll ask you to sign a consent form. You'll be given a copy of the information sheet and consent form to keep. You can change your mind and stop taking part at any time — you don't need to give a reason. Just let the team caring for your baby know. This will not affect the care your baby receives in any way.

If you choose to do the interview, we'll ask you to sign a separate consent form to allow us to record the interview. Please only agree if you feel comfortable. You can skip any questions you don't want to answer, and you can stop the interview at any time — just let the interviewer know. We will remove anything you say which might be identifiable from the interview transcript before data analysis to make sure your privacy is maintained. Audio recordings will be deleted when the interview has been transcribed.

After the interview, there is a 2-week "cooling off" period. During this time, you can still change your mind and ask for your interview to be withdrawn, and we will remove your data. After the 2 weeks, your information will be included in the analysis, and we won't be able to take it out.

Whether or not you take part — or decide to stop later — your baby's care will not be affected.

4. What do I need to know about taking part in this study?

The bath will happen on a day that's planned but at a time that works best for you. We want you to take the lead in bathing your baby, and a research nurse or your baby's regular neonatal nurse will be there to help you. After the bath, we ask that you wait at least 30 minutes before doing skin-to-skin cuddles with your baby. This is to stop your own skin germs from mixing with your baby's right after their bath. We encourage skin-to-skin cuddles at all other times during your baby's stay.

We will take small skin swabs from your baby, which will have a special study number instead of their name. These samples will go to a lab to count the different types of germs on the skin. A few of these samples will be tested in a special way called metagenomics. This test looks at the genetic material (RNA/DNA) of the germs to see exactly which ones are there. This helps us decide if we want to use this test in future studies. We will not be looking at your baby's own DNA. All information from this test will be kept anonymous.

5. What will I need to do if I want my baby to take part?

You will need to be there to bathe your baby, but if you can't be there for one of the baths, you can choose to give permission for the research nurse to bathe your baby instead. If you don't want the

nurse to do the bath, that's absolutely fine — you can still take part in the study. We simply skip that bath, and continue with the next bath you can be there for.

6. What are the possible benefits of taking part?

Taking part in this study could have benefits for both your baby and you. For your baby, it might help lower the chance of getting an infection while they're in the neonatal unit. For you as a parent, you'll get support to bathe your baby regularly while they're in hospital, which can help you feel closer to them and more confident about looking after them when you go home.

By taking part, you'll also help us plan a bigger study to find out if bathing babies regularly in neonatal care really helps reduce infections. Your feedback can help make sure the bigger study works well for parents. We can't promise that the study will directly benefit you or your baby, but the information we learn will help improve care for babies in neonatal units in the future.

7. What are the possible disadvantages and risks of taking part?

Taking part in this study has very little risk. Bathing babies is already a normal part of care in neonatal units. This study is just trying to find out how often babies should be bathed to help lower their chance of infection.

Bathing a baby in neonatal care can sometimes cause changes like a faster heartbeat or breathing, or affect their body temperature. We will watch your baby very closely during and right after the bath to make sure they are safe and doing well. If you or your baby's medical team feel that the baths are too much for your baby, you can stop taking part in the study at any time. You don't have to explain why.

8. What if there is a problem?

If you have any complaints about how you were treated during the study, or if you think you or your baby have been harmed, your concerns will be taken seriously and dealt with. More details are in Part 2 of this information sheet. If you have any worries or complaints, please contact your study doctor.

9. Contacts for further information

Study lead investigator: Dr Katie Gallagher katie.gallagher13@nhs.net / katie.gallagher@ucl.ac.uk
Your doctor: Dr Judith Meek Tel. Number: 0203 447 6247
Your Neonatal Research Nurse: Dr Kathy Chant Tel. Number: 0207 679 6031

PART 2 - Supporting information

1. What happens if my baby becomes very unwell during the study period (*not related to the study*)?

If your baby becomes unwell while taking part in the study, they will skip their bath. Baths can start again later, but only if both you and the medical team feel your baby is well enough — and only if they are still within the 4-week study period.

If your baby becomes seriously unwell, you will be given the choice to continue or stop being part of the bathing study. If this happens, the study team will talk it through with you in more detail to help you decide what feels right.

2. What will happen if I don't want to carry on with the study?

You can choose to take your baby out of the study at any time, and you don't have to give a reason. This will not affect your baby's care now or in the future. If you decide to withdraw, you can tell the study team using the contact information at the end of this leaflet, or the clinical team looking after your baby. We will still keep the information collected up to that point. The swabs will be used in the study and then destroyed at the end of the study. If you wish to withdraw skin samples from the study, please contact the study team. No more swabs will be taken, and your baby won't have any more baths as part of the study.

If you took part in an interview and later change your mind **after** the 2-week cooling-off period, we won't be able to remove your interview data, as it will already be included in the study analysis.

3. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this via the hospital's Patient Advisory Liaison Service (PALS). Details can be obtained from uclh.pals@nhs.net.

However, if you remain unhappy or have a complaint about any aspect of this study and wish to speak to someone independent of the research team/hospital, please email the UCL or UCLH Joint Research Office on: research-incident@UCL.ac.uk

Every care will be taken in the course of this research study to ensure your safety. However in the unlikely event that you are injured in the course of the study, compensation may be available.

4. How will we use information about you?

We will need to use information from you and your baby's medical records for this research project. This information will include:

- your baby: name, age, sex, primary diagnosis, nutritional status (i.e. how often and how much your baby is being fed), weight, and antibiotic history.
- you: name, contact details, gender, age, ethnicity, how many weeks pregnant you were when you gave birth (your baby's gestational age), antibiotic history during pregnancy / labour

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. In rare cases, researchers may need to break confidentiality if they discover something that suggests someone is at serious risk of harm, including the person taking part in the study or someone else. If this happens, the researcher will tell you what action is being taken, unless doing so would put someone at greater risk.

University College London is the sponsor of this research. University College London is responsible for looking after your information. We will not share your information related to this research project with

any other organisation. We will keep all information about you and your baby safe and secure. Consent forms will be archived with restricted access. Online data will be stored in a secure, password-protected system, and we will follow all privacy and data protection rules.

5. International transfers

Your data will not be shared outside the UK.

6. How will we use information about you after the study ends?

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. We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

7. 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 will keep information about you that we already have. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. 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.

8. 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/ the [UCL website](http://www.ucl.ac.uk) or <https://www.ucl.ac.uk/legal-services/privacy>, by asking one of the research team, or by sending an email to katie.gallagher@ucl.ac.uk or Sponsor Data Protection Officer data-protection@ucl.ac.uk.

Further information can also be found at <http://www.hra.nhs.uk/patientdataandresearch> (if you are unable to access the internet and/or would prefer a paper copy, please ask us).

9. What will happen to any samples I give?

Skin swabs will be taken from your baby just before and after each bath. These swabs are being collected specifically for this study. Each sample will be labelled with your baby's study ID number (not their name) and stored in a freezer at the lab within the hospital. Once enough swabs have been collected from all the babies in the study, they will be tested and analysed together. Swabs will be destroyed at the end of the study in line with hospital protocol.

The results from these study swabs will **not** affect your baby's care. This is because babies in neonatal units already have routine skin swabs taken as part of their normal care. Any treatment your baby might need will be based on those routine tests — not on the results from this research study.

10. Will any genetic tests be done?

A small number of the skin swabs collected during the study will be tested using a special method called **metagenomics**. This test looks at the genetic material (RNA/DNA) of the bacteria on the skin to find out exactly which germs are there. This will help us decide if we should use this type of testing in

a future study. **We will not look at your baby's DNA** — only the DNA of the bacteria found on their skin. All results from this test will be stored anonymously, so no one will know which baby the results came from. You can choose **not** to take part in this part of the study and still take part in the rest of the study.

11. What will happen to the results of the research study?

The results from this study will help us plan a larger study about how often babies should be bathed in neonatal care. The results may be published in healthcare journals, presented at conferences, and shared on trusted websites or social media pages (such as University College London's). When we ask for your consent to take part, we'll also ask if you'd like to receive a copy of the study results. If you say yes, we'll contact you when the study ends and share what we found.

12. Who is organising and funding the research?

The research is sponsored by University College London and is funded by the National Institute for Health Research (NIHR). The neonatal healthcare professionals (nurses, doctors, allied healthcare professionals) in the team paid by the NIHR to conduct the study do not have any conflicts of interest.

13. How have patients and the public been involved in this study?

This study was suggested by both parents and neonatal nurses on our unit. Many parents told us they hadn't had a chance to bathe their baby in hospital, but really wanted to — and felt it would help them feel more confident as parents. Neonatal nurses said they needed better evidence to understand how often babies should be bathed to help lower the risk of infection, and to make sure care is more consistent across different neonatal units.

To help guide the study, we've set up a parent advisory group made up of parents whose babies were cared for in a neonatal unit. This group will help shape all parts of the study to make sure it stays focused on the needs of families.

14. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nottingham Research Ethics Committee.

15. Further information and contact details

You're welcome to ask any questions at any time, before, during, or after the study. Please speak to your study nurse or doctor, who can give you the most up-to-date information. If you'd like to read the research this study is based on, your study nurse or doctor can provide it. If you need more information or have any concerns while taking part, please contact one of the people listed below:

- Study lead investigator: Dr Katie Gallagher (katie.gallagher@ucl.ac.uk)
- Your Doctor: Dr Judith Meek Tel. Number: 0203 447 6247
- Your Neonatal Research Nurse: Dr Kathy Chant: Tel. Number: 0207 679 6031

If you decide you'd like to take part, please read and sign the consent form. You'll get a copy of this information sheet and the signed form to keep. Another copy of the consent form will be kept in your



baby's hospital notes, one will be stored with the study records, and one may be shared with the research sponsor (the organisation overseeing the study). If you're unsure or need more time to think about it, that's completely fine — just let us know.

Thank you