

Parent information Sheet

Diagnostic testing of Volatile Organic Compounds (VOCs) in Necrotising Enterocolitis. The DOVE Study.

Your baby is being invited to take part in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please ask us if there is anything that you do not understand or would like more information.

What is the purpose of the Study?

Necrotising enterocolitis (NEC) is an illness that affects premature or unwell babies causing inflammation of their gut. It is sometimes difficult to diagnose until later on in the disease. It would be very helpful to be able to identify children with the disease earlier as this would allow us to treat children with suspected NEC more effectively. We plan to look at the concentration organic chemicals called VOCs in your babies stool. In order to do this we will take small samples from their nappy.. This will be stored and the test will be done in batches later. The result of this test will not alter your baby's treatment. The analysis may lead to a rapid diagnosis bed-side test and may help us to choose more appropriate treatment for NEC in the future.

Why has my baby been chosen?

We are collecting stool samples from as many premature babies as possible in order to establish the level of VOCs in babies who go on to develop NEC and those who do not. Your baby is being invited to take part because as they are premature and we know that all premature babies are potentially at risk of developing NEC. By comparing the results of this test in babies showing features of NEC with those who do not we hope to find out if this test will be useful for identifying this disease earlier.

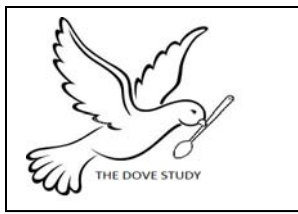
Do I have to participate?

No, you are free to refuse to take part in this study on behalf of your child. If you do not decide to take part it will not alter your baby's treatment in any way. If you decide to take part we will ask you to sign a consent form on behalf of your baby and give you a copy of this information sheet and the consent form for you to keep. If you decide to take part you are still free to withdraw at any time.

If you decide to take part in the study you baby's care will also remain the same.

What will happen if I agree to participate on behalf of my baby?

Your baby's treatment will continue as normal. If you agree to take part, a small sample of stool will be taken from your baby's nappy every day up to the time the baby is discharged. The samples will be stored in a freezer prior to analysis. If you have any concerns or complaints during the study please let the team know as soon as possible. You may wish to contact the PALS team also, you have the right to use the Hospital complaints procedure and they will be able to help you with this.



What are the possible side effects of taking part?

There are no side effects of this study. We do not expect there to be any benefits to individual babies taking part. However the information we hope to gain from this research may help the treatment of babies in the future.

Will the results of this study be kept confidential?

The researcher will need to examine your baby's medical notes to find out about what happened to your baby following the stool sample being taken. All information will be anonymous and your baby will not be identifiable in any publication. The baby's details will not be discussed outside the hospital.

What will happen to the results of the study?

The results of the study will not be known until the data is analysed. The results will be reported in professional publications or meetings but babies will not be individually identified. We will make our results widely available so that doctors and nurses can use the information to help babies in the future.

Who is funding and organising the research?

The study is funded by Action Medical Research Charity. The study is being organised by University of Birmingham.

Who has reviewed the study?

Action Medical Research Charity and West Midland Research Ethics Committee have reviewed and approved the study.

What do I do now?

Thank you for considering taking part in this research. If you have any further questions about the study please do not hesitate to contact me.

Contact Details:

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