Participant Information Sheet

Study title: Using the BUMPs (Best Use of Medicines in Pregnancy) pregnancy registry to monitor the safety of medication use in pregnancy

Invitation and brief summary: You are invited to take part in a new and exciting study to see if it is possible to collect information about the medicines you may be taking during pregnancy, and the outcome of pregnancy, directly from pregnant women and mothers. This may help us to perform more studies to better understand the safety of medicines when they are used in pregnancy.

Before you decide whether to take part, we would like you to read the following information so that you understand why the research is being done and what it would involve. This should take no more than 10 minutes. If it would help, a member of the research team would be happy to go through this information with you and answer any questions you have (contact details at the bottom of this page).

What is the purpose of the study?

Increasingly, pregnant women need to use medicine to treat longstanding medical conditions and stay healthy during pregnancy. Many women ask for information about how these medicines could affect their baby. For many medicines, there is often very little information available. Designing new ways of collecting this information is essential for improving the care of women, making sure they remain well during pregnancy, and helping to provide a healthy environment for their baby to develop. This study will investigate whether it is possible to collect the information we need directly from pregnant women and mothers.

Why do you want to collect information from me?

The safety of medicines in pregnancy is researched in different ways, but most of them have important weaknesses. For example, important information about lifestyle and/or over-the-counter medication use is often missing, information about the time the pregnancy occurred and even pregnancy outcomes can be inaccurate, and long-term childhood health and development outcomes are rarely available. A lot of information is taken from medical records, but it may be easier and more accurate to collect this information directly from you. You have been invited to take part in this study as you are pregnant and may be using medication. By taking part in this study, you will help us to assess what information is better collected directly and how suitable it would be to run such a system for monitoring the safety of medicines when used in pregnancy.

Do I have to take part?

It is up to you to decide if you want to take part. If you think you would like to take part, please read the rest of this information about this study, and then sign up to provide your information. You are free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive in the NHS or elsewhere.

What will I have to do if I take part?

If you do choose to take part, you will be invited to complete a series of short questionnaires completed via the internet (from either a computer or mobile device). Depending on how many weeks pregnant you are when you start to take part, you may be asked to complete between one and three short questionnaires during your pregnancy (one when you start, one at 14 weeks and another at 22 weeks), up to three short questionnaires during the first year after delivery (one shortly after your expected date of delivery, and if you have a live born child, one at 6 months and another at 1 year), then one short questionnaire yearly thereafter. We aim to follow-up live born children until they reach school age, as this will provide us with valuable information about early childhood development.

The information that you report will stay safe within the study and it will not be used to alter your medical care in the NHS or elsewhere. The information that you provide will not go into your NHS records. All the information you provide will be held securely, and shall not be disclosed to any party outside of the study team.

What are the possible benefits of taking part?

Taking part in the study will not help you in this current pregnancy, but the information you provide to this study may help improve the treatment of pregnant women in the future, and provide them with more information about the effects of medicines during pregnancy on women and their babies.

Could taking part pose any risks to me or my baby?

There are no physical risks to you or your baby from taking part in this research. It is important to mention that unfortunately not all pregnancies result in healthy babies, and if you are unfortunate to experience a bad outcome (for example, a miscarriage) then you may find that some questions cause upset or bring back bad memories. If you feel able, we would encourage you to complete information, even if the outcome has been poor or unexpected as it could help identify a safety concern. However, if you prefer not to provide any information we will understand and will not pressure you into providing information. If you feel that you would not like to tell us about your pregnancy outcome, you can let us know via the data collection system, or by contacting a member of the research team (contact details at the bottom of this page).

Will I receive any payments for taking part in this study?

You will not receive any payment for taking part in this research. You should not incur any costs with participating in this research.

How will we you use the information I provide?

We will need to use information from you for this research project.

This information will include your NHS number, name, contact details (email address), date of birth, and if you live in the UK, your postcode. We 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.

We will keep all information about you safe and secure.

Some of your information may be shared with researchers in another country. This will not include your identifying details (NHS number, name, contact details (email address), date of birth etc.). If your data is shared with researchers in another country, they must follow our rules about keeping your information safe.

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.

What are my choices about how my 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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records or other national electronic healthcare datasets. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

You can stop taking part in the study at any time. If you decide you no longer want to take part, we will continue to use the information that you have provided up to the time you stopped. You may also ask to withdraw information you have provided to the study, without providing a reason, and your information will be deleted. If you ask to withdraw your information, we will make a note of any reasons you supply in case it is valuable for improving the system in the future. To stop taking part in the study, you can let us know via the data collection system, or by contacting a member of the research team (contact details at the bottom of this page).

Will my taking part in this study be kept confidential?

Yes. We realise the importance of keeping personal information about you and your health in confidence. All information that you provide will be stored securely and in compliance with the

General Data Protection Regulations (GDPR) 2018. We will keep this information in the strictest confidence, and we will not share any identifiable personal information (for you or your child) with anyone else.

What will you do with the information I report?

We would like to keep details of your name and contact details so that we can get in touch about research projects in the future.

We would like to keep the information you provide for as long as the data collection system remains active. This information remains useful for monitoring the safety of medicines and can be combined with information that might be collected in other studies in the future.

We would like to be able to use the information you provide to access information held about you or your baby in national electronic healthcare datasets. This will be to compare the information you report against the information held in these national datasets, to test whether this method of data collection works, and also to fill in any gaps in the information you report.

We would like to be able to combine the information you provide about yourself and your child with data from other international research studies. This may result in the transfer of the information you report to another country, but identifying details for you and your child (such as names, dates of birth, residential location, email address) will not be shared with any third party.

What will happen to the results of the research study?

We will measure the success of this method throughout the first year of the study, and plan to describe our observations in a scientific report and/or peer-reviewed scientific journal article after the first year. Any reports published using data from the BUMPs registry will not identify individuals by name. We will include links to the findings of this research and provide a basic report of the findings on the BUMPs website. We will email you to let you know when the results of the study are available.

Who is organising the research?

The UK Teratology Information Service (UKTIS) and the Newcastle upon Tyne Hospitals NHS Foundation Trust are organising the research. No members of the research team will benefit financially from the study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. The original study has been reviewed and given favourable opinion by the North East - Tyne & Wear South Research Ethics Committee (REC reference number 24/NE/0025).

Who can I speak with if I have any questions?

If you have questions about this study, please speak with the researchers conducting this study.

Dr Jonathan Richardson (PhD): jonathan.richardson3@nhs.net 0191 213 7880 (UKTIS secretary Ms Jane Ingram)

Dr Sally Stephens (PhD): sally.stephens7@nhs.net 0191 213 7880 (UKTIS secretary Ms Jane Ingram)

If you prefer to raise your concerns with someone not involved in your care or this study, you can contact the Patient Advice and Liaison Service (PALS).

This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454

Email: nuth.patient.relations@nhs.net

Postal address: Patient Relations Department, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Freeman Hospital, Newcastle upon Tyne, NE7 7DN

Where can I find out more about how my information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ , or by asking one of the research team (email and contact telephone numbers above).