UK epilepsy & pregnancy REGISTER

WHO WE ARE

We are a group of doctors, nurses, psychologists, researchers and women with epilepsy who are interested to know how to make pregnancy as safe as possible for women with epilepsy and their babies.

WHAT DO WE DO

We recruit women with epilepsy who are pregnant to find out about their health and then later, the health and development of their child.

WHAT IS THE PURPOSE OF THIS RESEARCH?

To date we have enrolled over 11,000 women and their babies, finding out about the babies at birth. However, we are now running this study to test whether it is possible for us to follow up women and their babies for longer, to learn about the development of the children through to 2 years of age.

WHO IS ABLE TO TAKE PART?

You can take part if you have a diagnosis of epilepsy and are currently pregnant. You can be taking medications or not taking medication for your seizures. Participation in this study is completely voluntary and choosing not to take part will not affect you or your medical care in any way. You can also choose to withdraw your participation at any time, without giving a reason, and your care will continue as usual.

Around 2,500 women with epilepsy will have a baby each year in the UK. If you are one of these women, read on to find out how you can help. **Importantly, you do not need to change your medicines to take part.**

You can **join the register** using the QR code or see page 4 of this information sheet.

WHAT IS INVOLVED?

You can join the study at any time during your pregnancy; but earlier gives us even more information.

At the start we will ask some questions about your epilepsy and your background both before and during your pregnancy. Once your baby has been born, we will send a letter to your GP to ask about your child's health at birth and ask you some questions too.

Later, when your child is 3, 6, 12 and 24 months old we will send you some questions about feeding, health and how they are developing. You can choose to answer the questions online or if you prefer, we can complete them with you over the phone or via the post.

When your child is 24 months old as well as asking you to complete a questionnaire, we will also arrange a home visit. The assessment is completed with toys/games and so your child will feel like they are playing. This helps us assess the development of your child in more detail. At this visit we will also ask you about the health of your child and ask you to complete two problem-solving tasks which are like short quizzes. These help us to understand the thinking/reasoning skills your baby will have got from you.

Finally, we would like you to tell us what went well in this study and what improvements could be made. This will help us design the UK Epilepsy and Pregnancy Register for the next decade when we aim to recruit thousands of women with epilepsy to answer the most important questions around pregnancy safety for women with epilepsy. You can provide this feedback to us anonymously.

WORKING WITH OTHERS?

We believe that working with colleagues around the world gives us the best chance of improving the safety of women with epilepsy and their babies. Therefore, we ask to use anonymised data/ information we have collected in our study to combine with data/ information from women and children who have participated in similar studies in Norway and The Netherlands. This information would not include any information which could identify you or your baby. It would include data such as your child's developmental scores, medication and seizure information and would be combined with that same information from hundreds of other families. For this study, we are working with our partners at the Utrecht Medical School in The Netherlands who will provide the secure space for us to bring together data from different countries.

You will be asked about this directly on the consent form. You can take part in this study without giving us permission to share your anonymous data for future work with other doctors and researchers.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

By taking part you will be helping us learn about how to make pregnancy and breastfeeding for women with epilepsy as safe as possible. We will be able to reimburse you for completing each of the questionnaires about your child's development (£5 voucher) and for the play-based assessment (£10 voucher).

ARE THERE ANY RISKS TO TAKING PART?

The questions we ask you to complete are like those you will do with your Health Visitor. However, when asking about your child's development it may highlight areas where they may require additional support. In this situation we would encourage you to speak to your Health Visitor or GP if you have concerns or we, with your permission, would write to your Health Visitor on your behalf. This will make sure that your local health team are there to support you with your child's development.

WHO IS ORGANISING AND FUNDING THE STUDY?

The study is sponsored by Belfast Health and Social Care Trust and is being coordinated by the University of Manchester. The study is funded by educational grants from pharmaceutical companies, funding from the funding from the University of Manchester (ISSF Wellcome Pump Priming Fund), and the Innovative Medicines Initiative ConcePTION Study. The ConcePTION project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 821520. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

WHO HAS REVIEWED THE STUDY?

The study has been approved by an independent group of people, called a Research Ethics Committee, whose job is to protect your safety, rights, wellbeing and dignity, as well as by Belfast Health and Social Care Trust.

WHAT IF SOMETHING GOES WRONG?

If you have a concern about any aspect of this study or if something goes wrong and you want to tell us about your experience, we would ask you to contact the study lead Dr John Craig, Consultant Neurologist [UKEPR@manachester.ac.uk] who will do their best to answer your questions. If you have a complaint you wish to discuss with someone other than our team you can contact the lead hospitals complaints team[complaints@belfasttrust.hscni.net].

WHAT WILL HAPPEN TO MY INFORMATION?

We will need to use information from you, your medical records and your GP for this research study. This information will include your and your child's:

- Name
- NHS/HSC/CHI number
- Contact details
- Gender
- Ethnicity
- DOB

Due to the gap in times we will be contacting you we will use this information to check your and your child's current address and health status with your GP before we send each questionnaire. We will also use this information to do the research or to check your records to make sure that the research is being done properly. All information collected about you and your family will be kept safe, secure and strictly confidential. People who do not need to know who you are, will not be able to see your name or contact details. Data collected about you will be recorded against a number unique to you and not your name. Information which can identify you such as your name, address and date of birth (or your baby's identifiable information) will be collected so we can contact you, but it will be stored separately so that your questionnaire responses will remain anonymous.

Whilst the information you provide on this study is confidential, if we are concerned about you or your child's safety, health or wellbeing we will contact your local health team (e.g., GP, Health Visitor, Social Worker) to ensure that you get the help and support you and your child need.

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. The information we collect about you and your child will be used along with data from other families. We will store the information we collect about you and your child' health and development securely for 20 years. With your agreement, we will keep identifiable information such as names, addresses and dates of birth for 10 years to allow us to contact you about participating in any follow-up studies on this topic. We store the information in a secure database which is held and looked after by the University of Manchester. If you gave your permission, some of your information will be sent to Utrecht Medical School in The Netherlands. They must follow our rules about keeping your information safe and this will not be information which could identify you or your baby.

Belfast Health and Social Care Trust is the data controller for this study which means that they decide why and how the data is being collected and what it is used for. Under information laws you have several rights, for example, asking for a copy of the information held about you. If you would like to find out more about your rights, please contact the Data Protection Officer at DataProtection@belfasttrust.hscni.net.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

If you wish stop being part of the study you can stop at any time, without giving a reason, but we will keep information about you that we already have. You can let us know you wish to stop by contacting us by either phone or email. Your health care will not change depending on whether you withdraw or not. 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 as part of the UK Epilepsy and Pregnancy Register.

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/

- From our leaflet available from www.hra.nhs.uk/patientdataandresearch

https://belfasttrust.hscni.net/about/access-to-information/data-protection/

- By asking one of the research team
- By sending an email to [email], or
- By ringing us on [phone number].

WHAT ABOUT FUTURE STUDIES?

If this pilot study is a success, we will be including a longer term follow up for all the women and children who join the Register. Children change a lot across childhood, and they learn new skills as they grow. Currently, we can only follow up your child until 2 years of age, however if in the future we are able to follow them up for longer we will get in touch and ask you if you would be happy to take part for longer.

HOW WILL I FIND OUT ABOUT THE RESULTS?

We will send out a summary of the results of this study to everyone who took part as a newsletter via post and email which will include a link to a video clip which will also summarise the results. We will make the results available to the epilepsy community in the UK more widely by working with charities and doctors to ensure that as many people as possible know about the results.

I WANT TO TAKE PART, WHAT SHALL I DO?

To join the Register please take a picture of the QR Code below and this will take you to our website.

Alternatively, you can look at our website, give us a call or send us an email: UKEPR@manchester.ac.uk

Or visit our website:
www.epilepsyandpregnancy.co.uk

Or give us a call: 0800 389 1248