Trust logo

Preterm Clinical Network Cohort Research Programme (PCN-CRP)

PARTICIPANT INFORMATION SHEET

Chief Investigator: Prof Andrew Shennan, King's College London

Local principal investigator*:* "insert researcher name here"

We are inviting you to take part in a research study or trial. To help you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully. Talk to other people about the study if you want to. You can contact us if there is anything that is not clear, or if you would like more information. Take time to decide if you want to take part.

Invitation to take part

This Preterm Clinical Network Cohort Research Programme brings together a series of studies aiming to reduce preterm birth and the problems women and families can experience because of it. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your hospital team if you wish. Ask us if there is anything that is not clear or if you would like more information. You will be given as long as you need to read the patient information sheet and consider participation.

What is the purpose of this programme?

The programme aims to investigate ways to improve care for women and families at risk of preterm birth. The programme will strengthen our efforts to find solutions quickly, to evaluate new potentially useful tests and treatments and to get them into practice as quickly as possible.

Why have I been asked to take part?

You have been asked to take part because you are pregnant and may have an increased chance of having your baby earlier, either because you have risk factors, e.g. have had a baby early before or surgery on your cervix, or because you have symptoms that might be preterm labour.

Do I have to take part? No. It is up to you to decide to take part. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you can still withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. If you wish to withdraw, please contact your local Principal Investigator (named above) and/or the Chief Investigator, Professor Andrew Shennan at andrew.shennan@kcl.ac.uk.

What taking part involves

If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without having to give a reason. ***You can choose to be in one or all of the studies that are included in this programme, if you are eligible for them.*** Your doctor or midwife will tell you which ones you are

eligible for. They will give you more information about why we are doing the sub-study, what would happen to you if you took part, and ask you to sign a supplementary sub-study consent form.

We will ask your permission to look at your medical notes and those of your baby after delivery so that we can find out what happened. If you have your baby in a different hospital we might need to contact your GP or the hospital where you have the baby. We will collect information about the care you receive during pregnancy, which may include scan images of your cervix.

What are the possible benefits of taking part?

Taking part in this programme is unlikely to have direct benefit for you or your current pregnancy. What we learn, however, might help us to improve care for you in any future pregnancies as well as for other women, and reduce the number of babies being born too early.

What are the disadvantages or side effects of taking part?

We are collecting information about you and the maternity care you receive so we can learn more about preterm birth prediction and prevention. Any possible side effects of the clinical tests and treatments you receive will be explained by your doctor or midwife. Any possible disadvantages or side effects of taking part in any of the programme sub-studies will be explained in the additional information sheet you will be given.

What if I change my mind after agreeing to take part?

You are free to withdraw at any time without your medical care being affected. If you change your mind we will not be able to withdraw your information from any research analysis that has already been carried out, but we will not include it in any research that starts after you have withdrawn your consent.

Further Supporting Information

The information will be stored on the PCN-CRP database and PCN-CRP participant details database which are secure web-based platforms provided by Omda (previously known as MedSciNet), a Stockholm based company specialising in design and development of web applications and online database systems for clinical trials and studies. The data will be held on these databases, and downloaded to a university Sharepoint site for analysis.

Information on the use of data

How will we use information about you?

We will need to use information from your & your child's hospital medical records for this research programme. We will collect information on your previous medical history and pregnancies, your maternity care e.g. whether you had any other treatments relating to preterm birth, details about the birth e.g. onset of labour and how many weeks pregnant you were when the baby was born, and whether you and/or your baby had any problems or needed extra care e.g. admission to neonatal unit. We will collect this information during your pregnancy, e.g. whenever you attend specialist preterm clinic appointments, and after your baby has been born.

This information will include your initials, date of birth, hospital number and NHS number, but these identifiers will be kept on a separate but linked participant details database. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will also keep your name and contact details on this separate, but linked database, if you have indicated that you agree to this on the consent form.

People who do not need to know who you are will not be able to see your or our child's name or contact details. This will be replaced with a code number.

We will keep all information about you & your child safe and secure.

Some of your & your child's information will be sent to Sweden, where the servers for the main study and participant details databases are located. They must follow our rules about keeping your information safe. Appropriate safeguards will be in place, and the legal basis for storage of this data is that "it is a task in the public interest".

Once we have finished the sub-studies, 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.

Your data will be stored at KCL for a minimum of 25 years. The study data will then be securely archived.

If you have consented to your information being shared for future research purposes, this will only be shared with third party researchers who have been approved by the Preterm Clinical Network (PCN) Database Access Committee. This is a special group of people, which includes experts in preterm birth and a patient representative. They consider applications from researchers and only allow release of data if they approve both the researchers and their project.

What are your choices about how your information is used?

- You can stop being part of the programme at any time, without giving a reason, but we will be unable to remove any information that has already been included in research analysis.
- 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.
- If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation(s)) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to ask if you want to take part in another research study. You might then be asked if we can give your contact details to another research team within Guy's and St Thomas' NHS Foundation Trust or King's College London. Agreeing to be contacted does not commit you to agreeing to take part in further studies.
- You will also have the option to allow us to use your NHS number to follow up your future health status using routinely collected health records, This will help us to understand longer term consequences of any conditions experienced during pregnancy, for example, infection, or treatments used to reduce the risks associated with preterm birth.

Where can you 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/
- Visiting the Health Research Authority website at:
- https://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/
- our leaflet available from: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx (For GSTT) and https://www.kcl.ac.uk/research/research-environment/rgei/research-ethics/use-of-personal-data-in-research (for KCL)

- by asking one of the research team (contact details included below)
- by contacting the Data Protection Officer: (For GSTT: Nick Murphy-O'Kane DPO@gstt.nhs.uk; For KCL: Olenka Cogias info-compliance@kcl.ac.uk)

What if there is a problem?

If you have a concern about any aspect of this programme, you should ask to speak to your local Principal Investigator who will do their best to answer your questions [*insert name and email address*]. If you remain unhappy and wish to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing or you can do this through your local hospital Patients Advice and Liaison Service (PALS) [*insert details*].

In the event that something goes wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen to the results of the research study?

The results will be published in the medical literature and presented at conferences. *No participant names or identifiable information will be included.* We will write a summary of the findings of the study and make it available on the study website (www.medscinet.net/ukpcn). Results will also be published through university, clinical and service user networks using email and social media.

Who is organising and funding the research?

Tommy's charity is funding the research, with sponsorship from King's College London and Guy's and St Thomas' NHS Foundation Trust.

Who has reviewed the study?

This study has been reviewed and approved by this NHS Trust's Research & Development Department. Health Research Authority and NHS Research Ethics Committee (REC Ref: 25/YH/0008; IRAS ID 344400).

If you have any further questions about the study please contact *[insert name]* on phone: *[insert phone number]* or email*: [insert email address].*

Independent contact details:

If you would like to speak to an individual who is independent of the study team about this study, please contact [insert contact details].

Thank you for reading this participant information sheet. Please keep a copy for your records.

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