Postnatal Instead of Normally-timed Cervical Screening-2 – the PINCS-2 study

Participant Information Sheet (PIS)

You are being invited to take part in a research study about cervical screening after birth.

We want to find out if it is acceptable to offer cervical screening at 6 weeks after delivery. This is a time when people already attend their GP practice for a postnatal check-up for themselves and their baby. We also want to see if urine tests and vaginal swabs are as good as the usual cervical screening test taken by a nurse or a doctor. The research findings will form part of a PhD thesis.

Before you decide to take part, it is important you understand what the research involves and why it is being done. Please take time to read this information carefully before deciding to take part. You can discuss it with others if you wish. Please ask if there is something that is not clear or if you would like to know more. Thank you for taking the time to read this.

About the research

Who will conduct the research?

Dr Jo Morrison and Dr Victoria Cullimore from Somerset NHS Foundation Trust are leading this research.

Local research team details:

Study summary:

- Cervical screening is a test to help prevent cervical cancer. It can save lives, but only 6-7 in 10 people in the UK invited go on to have the test. This is the lowest number for 20 years.
- A cervical screening test, or 'smear test', involves collecting cells from the cervix (neck of the womb) with a soft brush. The cells are tested for high-risk human papillomavirus (HPV), which can cause cervical cancer.
- Uptake for cervical screening is lower for people who have had a baby in the last 5 years. Half of people will be due a smear test by the end of their pregnancy. And, most of these people will still not have their cervical screening by the time their baby is 6 months' old.
- New mothers and GP practice staff asked us if the cervical screening test could be done at the 6-week postnatal check-up. At the moment, cervical screening tests are not taken until 12 weeks after birth, but there is no evidence that 12-weeks is the best time to offer cervical screening with modern HPV tests. We would like to do some research on this to help find out.
- New parents also asked if they could take a self-test, rather than have a normal cervical screening test. This might avoid the need for a vaginal (internal) examination, using a speculum to see the cervix. Self-sampling tests have been developed and could remove many of the current barriers but aren't yet part of clinical practice outside of trials. They have the potential to save lives by increasing the number of people who decided to get tested in cervical screening.

The purpose of this research is to:

- Explore if people would be willing to have a cervical screening test 6 weeks after birth
- Get feedback about the experience of testing at 6 weeks after birth

- Explore peoples' thoughts on urine self-testing and vaginal self-taken swabs for cervical screening
- Explore how accurate urine self-tests and vaginal self-taken swabs are compared to cervical screening tests taken by a nurse or doctor
- Understand the barriers to attending cervical screening and how we can make it better

The results of this study will tell us how best to perform a larger study. We hope the research will be able to change the NHS Cervical Screening Programme and that this will mean people that want to have screening at their postnatal check-up are able to. We know that this won't be the right time for everyone and people would have the option to wait longer, if that works better for them.

We will also ask to keep your urine and vaginal swab samples in a biobank, for use in future studies that may help us understand their accuracy and application better.

Am I suitable to take part?

We invite anyone who is due to give birth or has given birth within the last 6 weeks to take part. You must be between 24 ½ years and 65 years old at the time of the 6-week postnatal appointment.

Participants need to have a cervix (not had an operation to remove the neck of the womb).

Participants must be able to communicate in English, or have a relative/friend/carer acting as interpreter. Information will be available in languages other than English, if requested, and it may be possible to provide an interpreter, subject to local resources.

It doesn't matter if you have had cervical screening tests before, what the results were or if they are up-to-date.

Do I have to take part? Can I change my mind?

Taking part in this study is completely voluntary and will not affect your current or future medical care. If you initially decide to take part but change your mind later, you can stop participating at any time. Any information that you have given up to that point will be used in the study results.

To contact the team to stop participating please call or email:

What will happen to the results of the study?

The results of the study will be published in a scientific journal and as part of a PhD thesis. We will also share the study with charity partners so the results can be distributed more widely. You will not be identified in any reporting of results. If you would like a general summary of the results of the study when they are available, you can ask the research team and they will make a note of this.

Who has reviewed the research project?

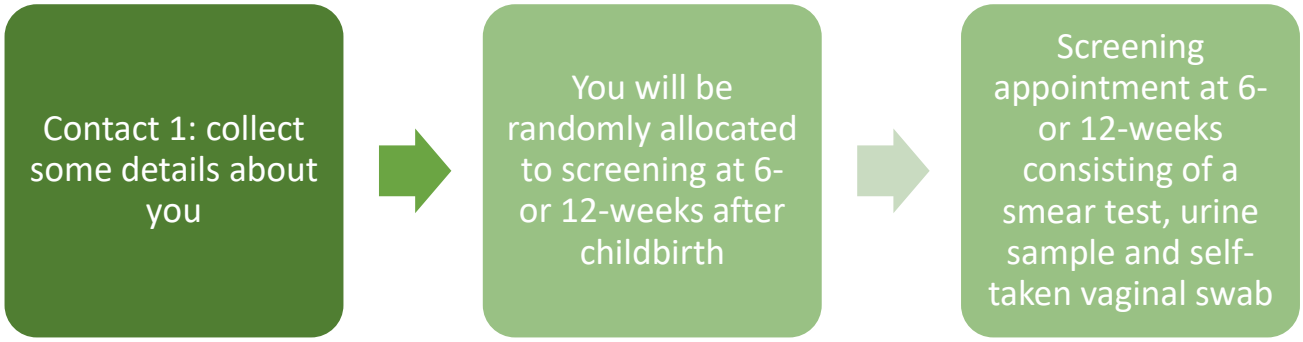
All research in the NHS is approved by the Health Research Authority (HRA) and reviewed by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been through ethics review and has been given a favourable opinion by the London-Stanmore Research Ethics Committee on05/04/2024.

Who is funding the research project?

This study is sponsored by Somerset NHS Foundation Trust and funded by the Medical Research Council (MRC). Other members of the research team are based at North Bristol NHS Trust, University of Manchester, Queen Mary University, London, and University of Birmingham

What would my involvement be?

What would I be asked to do if I took part?



The study team will go through any questions with you and if you are happy to take part will ask you to complete a consent form. As part of this consent, we will ask to have access to your maternity records and medical records/cervical screening records, but only for information pertinent to this study.

You will be asked to complete a short survey about your background, previous and current pregnancies, if you've had cervical screening before and if you had the HPV vaccination, from what you can remember. It will also ask about the logistics of you attending appointments.

You will then be randomly allocated by a computer program to the 6- or 12-week group. This means you could be asked to have your screening appointment (smear test, urine sample and vaginal swab) at 6 or 12-weeks after childbirth. Half of the participants in the study will be allocated to each group.

The research team will call you a few weeks after you have had your baby to arrange your screening appointment. They may call or text you to confirm the time, date and location with you.

Screening appointments

If you decide to take part, you will be invited to a screening appointment. If you prefer support (such as from family members, friends or carers) you can bring someone else along too. You will be asked if you are still willing to continue the study.

You will be given a urine test kit to perform a urine sample. This comes with instructions – please ask if you have any questions. An instruction video is available via this link (https://sites.manchester.ac.uk/aces/).

You will also be given a kit to take a vaginal sample to perform after the urine sample. This also comes with instructions, and we can help explain the process if you have any questions.

A qualified smear-taker (doctor or nurse) will take a regular cervical screening test (taking a sample of cells from your cervix).

You will be asked to complete an online survey for your views about the three different tests before you leave your appointment. The research doctor or nurse will show you what you need to do and can help you with this. It will take about 5 minutes. If you would prefer a paper form, they can give you one to complete and they can upload this for you after your appointment.

If your cervix looks abnormal at this appointment, you will be referred for colposcopy, where a microscope is used to examine the cervix in more detail and special dyes are applied to identify abnormal cells.

The results of the urine tests and vaginal swabs will not be made available to you or your local study team, as these are just for research. After the results are sent to the research

team, the samples will be stored for future research. All samples will be labelled with your study number only so no future research would gain identifiable information about you. Researchers can apply to use these samples for their research in the future after going through a formal application and ethical review by an independent committee.

The results of the cervical screening test will be sent to you by letter, along with any recommendations for follow up. Normally, we would not examine the cells, if your cervical screening test is HPV negative. In this study we will look at the cells for all participants, regardless of the HPV test result. We will communicate the test results as per the normal NHS cervical screening protocol, but if there are any changes picked up incidentally, that require further investigation, we will let you know about this too.

If your smear test was due at the end of your pregnancy, we will reset your 'next test due date', if you are randomly allocated to have your test done at 12-weeks. If you are not overdue, we will not reset your next test due date and your next smear test would be when it would next normally be due (3-5 years after your last normal test, prior to the study). If your cervical screening is not due, or you are allocated to a test at 6-weeks, the study test will be in addition to your normal screening programme tests and may result in you needing further appointments to check your cervix, that you might not otherwise have had.

By taking part in the study, there may or may not be any immediate benefits to you. Most people will have a normal result, but for those with an abnormality this will be picked up sooner.

The results of the study could help shape the Cervical Screening Programme and make it more convenient for new parents to have their smear tests in the future. It also helps us know more about the views towards self-sampling (e.g., a urine sample) for cervical screening is acceptable.

Will I be compensated for taking part?

If you choose to take part, you will be able to claim £30 compensation after completion of the screening visit. We will provide you with details of how to claim your £30 compensation.

What happens if I do not want to take part or if I change my mind?

It is up to you if you want to take part and are not obliged to do so. If you decide not to take part, it would be helpful for us to know why, if you are happy to tell us. You are free to withdraw at any point without giving a reason. However, if you are able to tell us why, via a short questionnaire, we would be very grateful as this would be useful information, to help design the NHS cervical screening programme to work better for people in the future.

If you lose capacity to consent whilst taking part in the study, you will be withdrawn from the study and any identifiable data and tissue that has been collected with consent will be retained and used. No further data or tissue will be collected and no further study activities will occur.

Data Protection and Confidentiality

How will we use information about you?

We will need to use information from you, and from your medical records and NHS cervical screening and immunisation records, for this research project.

This information will include your:

- Your NHS number, name and contact details;
- your cervical screening and HPV vaccination history and any other cervical screening results during the study period;
- the results of the HPV tests for both the urine self- test and the clinician-taken cervical sample;
- the results of cytology for the clinician-taken cervical sample;

- the results of any colposcopy examination and biopsies;
- details about previous and most recent pregnancy and mode of deliveries.

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.

We will keep all information about you safe and secure.

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 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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your NHS cervical screening record and your hospital about any subsequent cervical screening and colposcopy treatments during the study period. 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.

You can choose to opt out of your samples being stored for future research in the biobank.

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/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to PINCSStudy@somersetFT.nhs.uk, or
- by contacting us on 07443 725448
- by writing to:

  PINCS study
  Research Department
  Musgrove Park Hospital
  Somerset NHS Foundation Trust
  Taunton
  TA1 5DA

Please also note that individuals from Somerset NHS Foundation Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

If you have a concern or complaint that you wish to direct to members of the research team, please contact:

- Dr Jo Morrison (Chief Investigator), GynaeOncSecAdmin@Somersetft.nhs.uk with 'PINCS Study complaint' in the title

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

- The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.
- If you wish to contact the PALS team, please contact PALS@SomersetFT.nhs.uk or from the PALS website https://www.somersetft.nhs.uk/contact-us/contact-us-and-get-involved/pals/

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s):

Central Research Study Team

- Dr Victoria Cullimore (Clinical Research Fellow), PINCSStudy@SomersetFT.nhs.uk (with 'PINCS study query' in the subject of your email).
- Dr Jo Morrison (Chief Investigator), PINCSStudy@SomersetFT.nhs.uk (with 'PINCS study query' in the subject of your email).

Thank you for taking the time to read this information and considering whether or not you would like to take part in this study.
