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Postnatal Instead of Normally-timed Cervical Screening (PINCS)

Submission date 11/03/2024	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/03/2024	**Overall study status** Ongoing	
Last Edited 04/06/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Cervical screening is a test to help prevent cervical cancer. It can save lives, but only 7 in 10 women, and people with a cervix, in the UK have the test when invited. 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. About half will be due a smear test by the end of their pregnancy and most 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 'smear' test. This might avoid the need for a vaginal (internal) examination, using a speculum to see the cervix. Self-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 smear test 6 weeks after birth
• Get feedback about the experience of testing at 6 weeks after birth
• Explore if people would be willing to have another test at 12 weeks after birth to compare between 6 and 12 weeks
• Explore peoples' thoughts on urine self-testing for cervical screening
• Explore how accurate urine self-tests 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. We hope this will mean people that want to have screening at their postnatal check-up can. We know that this won't be right for everyone. People would have the option to wait longer, if that works better for them.

Who can participate?
Women who are 24.5 years old or more, who are pregnant or within 6 weeks of delivering their baby, and who have not had their cervix removed.

What does the study involve?
In PINCS-1 consenting participants will have a speculum examination and cervical sample (smear test) taken at 6 weeks after birth. They will also be offered urine self-testing for Human Papillomvirus (HPV), the virus that causes abnormal cells on the cervix. Repeat cervical screening and urine testing will be offered at 12 weeks postnatal for matched samples to determine diagnostic test accuracy of sampling and urine HPV testing at 6 weeks postnatal.

Phase 2 of the study - PINCS-2 - will test the feasibility of randomising participants to either 6 or 12 weeks cervical screening to inform whether further studies can be individually randomised, or whether a cluster randomised design will be needed, to test the effect on uptake rates of screening and longer-term clinical effects on subsequent screening outcomes and development of pre-cancerous cervical intraepithelial neoplasia (CIN).

What are the possible benefits and risks of participating?
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. For those due a smear by the end of their pregnancy, the 12-week test in the study will count as their routine test, so they won't need to book another appointment with their GP practice.
There is a small risk that we might find a change in your cervical screening test which leads to a referral to a colposcopy clinic in a hospital, so that someone can look at your cervix very carefully and possibly take a biopsy. However, this is also a benefit, if, more rarely, a more serious change was found, as you could be offered treatment to prevent cervical cancer 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

Where is the study run from?
Somerset NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2019 to December 2026

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Jo Morrison, jo.morrison@somersetft.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Jo Morrison

ORCID ID

https://orcid.org/0000-0003-0000-520X

Contact details
Dept of Gynaecological Oncology, GRACE Centre, Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA
-
jo.morrison@somersetft.nhs.uk

Type(s)
Public

Contact name
Dr Victoria Cullimore

Contact details
Dept of Gynaecological Oncology, GRACE Centre, Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA
-
PINCSStudy@somersetft.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321696

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60494, MR/X030776/1, IRAS 321696

Study information

Scientific Title
Investigating the acceptability and accuracy of cervical screening and self-sampling in women at 6-weeks postnatal - PINCS

Acronym
PINCS

Study objectives
This is a 2-phase feasibility study to evaluate the acceptability and feasibility of offering cervical screening with HR HPV testing at 6-weeks postnatal. Feedback from new mothers, during a

quality improvement project, suggested that more women would access cervical screening postnatally if this could be provided at the time of the routine 6-week postnatal baby check.

In part 1, this study will assess the feasibility of a larger trial to assess the diagnostic test accuracy of a paired sample study, screening at both 6 and 12 weeks postnatal.

In part 2, we will assess the acceptability and feasibility of an individualised randomisation trial comparing screening at 6 and 12 weeks postnatal.

These data will inform the design of subsequent studies to see how offering screening at the time of a 6-week routine postnatal check up might improve cervical screening uptake, which is at historically low levels in this age cohort.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/04/2024, Stanmore REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048129; stanmore.rec@hra.nhs.uk), ref: 24/LO/0206

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Cervical screening

Interventions
To understand reasons for non-participation and establish an up-take rate, a sub-study cohort of 100 potential participants will all be approached and the acceptance rate recorded. The reason given by who choose to not participate will be recorded anonymously for those willing to disclose reasons.

At appointment 1, potential participants will discuss the study with a member of the research team, and if willing to take part, consent will be obtained and they will complete a 1-page questionnaire.

After delivery, a member of the study team will contact the participant to confirm ongoing willingness to participate and arrange a 6-week screening appointment. A reminder notification will be conveyed in advance of the appointment.

At appointment 2, 6-weeks after delivery, consent will be confirmed and the participant will perform self-testing with Coli-pee sampler. A speculum examination will then be performed and a cervical sample taken using a cervical brush. Samples will be collected in accordance with the NHS CSP guidance by members of the study team who are registered on the Cervical Sample Takers Database.

The appointment plan for 12-week screening will be confirmed, and further appointment made. Following the appointment, the participant will complete a web-based questionnaire. A reminder notification will be conveyed in advance of the next appointment. Participants will be made aware that the results of the cervical screening test will not be available until after thier 12-week test is performed.

At appointment 3 at 12-weeks postnatal a Colli-pee urine sample and cervical sample will be taken with a cervical brush. The participant will be informed of the management process in the case of an abnormal smear result. Following the appointment, the participant will complete a web-based questionnaire. Participants will receive a letter containing their cervical screening results and information on continuation of care under the NHS CSP, copies of which will be sent to the screening laboratory and their GP, to ensure safe onward care.

The urine samples will be sent for laboratory analysis. The results will form part of the study data analysis, but the results will not be available to the local study team or study participants. No clinical action will be required based on the results of the urine tests, and the results will not affect the NHS CSP NTDD.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To evaluate the acceptability and feasibility of a paired study design
1. Acceptability:
1.1. Recruitment and completion rates of undergoing testing at 6 and 12 weeks in the study.
1.2. Acceptability will be measured via a patient-reported outcomes questionnaire following testing at 6 and 12 weeks postnatal, including a 10-point visual analogue pain scale
2. Feasibility: How many women need to be approached for one to consent? Measured using study records

Secondary outcome measures
1. Evaluate acceptability of clinician-taken cervical samples and urine self-screening tests in those who decline, in those who consent both at 6- and 12-weeks using questionnaire data (measured in a 100-patient sub-study of all of those approached about the study)
2. Assess the quality of cervical samples from clinician-taken samples at 6-weeks postnatal against standard NHS Cervical Screening Programme criteria

3. To determine the agreement in HR HPV status at 6- and 12-weeks postnatal between clinician-taken cervical samples and self-testing using urine tests (using a 2-by-2 table to test for sensitivity, specificity, negative and postitive predictive values)

Overall study start date
13/12/2019

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. 24.5 to 64 years
2. Has a uterine cervix and eligible for cervical screening
3. Currently pregnant or recently delivered
4. < 6 weeks postpartum
5. Valid informed consent to cervical screening at 6 and 12 weeks postnatal

Participant type(s)
Patient

Age group
Adult

Lower age limit
24.5 Years

Upper age limit
64 Years

Sex
Female

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria
1. < 24.5 years old
2. Absence of uterine cervix or ineligible for cervical screening
3. Lack of valid informed consent to screening at 6 weeks postnatal

Date of first enrolment
11/06/2024

Date of final enrolment
01/01/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Sponsor information

Organisation
Somerset Partnership NHS Foundation Trust

Sponsor details
Musgrove Park Hospital
Taunton
England
United Kingdom
TA1 5DA
+44 (0)1823333444
research@somersetft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.somersetft.nhs.uk/

ROR
https://ror.org/05jt6pc28

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We plan to publish the results in a high-impact peer reviewed journal within 12 months of the study end date and share results via Gynaecological Oncology Charities social media channels, once the study is published

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request, jo.morrison@somersetft.nhs.uk. To ensure participant anonymity is safeguarded and subject to any reasonable and necessary delay, pseudonymised research data will be securely archived in a repository following publication of the results where they will be stored indefinitely. These data may be used in future research, here or abroad. Before database lock, the database will be reviewed to ensure all queries have been resolved and the dataset is complete. The Data Management will be compliant with Somerset NHS Foundation Trust's policy.
The PI will retain all essential documentation pertaining to the study for 10 years as per the Sponsor's policy. This documentation will include copies of protocols, correspondence, CRFs, records of consent, original reports of test results and any other documents related to the conduct of the study. Documents will be stored digitally, or if hard copies, in locked filing cabinets, which will be able to be accessed and data retrieved at a later date if required. Digital forms will be encrypted or stored on Trust secure servers.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.7	02/04/2024	09/04/2024	No	No
Participant information sheet	version 2.1	05/04/2024	02/05/2024	No	Yes
Protocol article		30/05/2025	04/06/2025	Yes	No