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Using a light-based scan to assess changes in the cervix during pregnancy and understand whether it could help predict when labour may start

Submission date
08/02/2026

Recruitment status
Recruiting

Registration date
28/09/2026

Overall study status
Ongoing

Last Edited
25/09/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The cervix is the lower part of the womb. During pregnancy, the cervix normally changes and softens as the body prepares for labour and birth. These changes are partly related to collagen, a strong protein that helps give the cervix its structure. At present, there is no simple clinic test that can directly assess how collagen in the cervix is changing during pregnancy.
This study will test a new light-based scanning device called polarisation-sensitive optical coherence tomography, or PS-OCT. The device is designed to assess collagen in the cervix. The aim of the study is to find out whether cervical PS-OCT can be used to obtain high-quality measurements, whether the measurements are repeatable, and whether women find the assessment acceptable during pregnancy. The study will also compare PS-OCT measurements with laboratory tests on cervical tissue samples.

Who can participate?
-Women aged 18 to 54 may be able to take part.
-The study includes non-pregnant women having a hysterectomy for a benign condition that is not related to cervical disease; pregnant women attending antenatal clinics or the preterm birth clinic who are between 20 and 28 weeks pregnant and may be at risk of preterm birth; and a smaller group of pregnant women from the study who will be invited to take part in an interview about their experience of the PS-OCT assessment.
-Women will not be able to take part in the pregnancy part of the study if they have a twin pregnancy, are unsure how many weeks pregnant they are, have a clinical vaginal infection, are currently taking antibiotics, have active vaginal bleeding, or have ruptured membranes.

What does the study involve?
The study has three related parts.
-In the first part, cervical tissue samples will be taken from women who are already having a hysterectomy for benign, non-cervical reasons. The tissue will be scanned using the PS-OCT device and then examined in the laboratory using microscope-based tests. This will help the

researchers compare the PS-OCT findings with established methods for assessing collagen in tissue.
-In the second part, pregnant women will have a PS-OCT assessment of the cervix during a routine antenatal or preterm birth clinic visit between 20 and 28 weeks of pregnancy. The PS-OCT probe has a sterile disposable cover and is gently inserted into the vagina so that the cervix can be scanned. Four measurements will be taken from different areas of the cervix. For some participants, measurements may be repeated by the same or a second trained member of the research team to assess the consistency of the readings. Each set of readings is expected to take less than three minutes.
-In the third part, a smaller group of pregnant participants will be invited to take part in a questionnaire or semi-structured interview about their experience of the PS-OCT assessment. This will include questions about comfort, anxiety, embarrassment, any symptoms afterwards, and reasons for taking part. The interview will take place within 2 to 4 weeks after the PS-OCT assessment and may be by telephone or face to face.

What are the possible benefits and risks of participating?
-Participants are not expected to benefit directly from taking part in this study. However, the information collected may help researchers develop better ways to assess changes in the cervix during pregnancy in future studies. This could help improve understanding of preterm birth risk and readiness for labour.
-The PS-OCT assessment uses light to scan the cervix and is considered low risk. The device uses a sterile disposable cover to reduce the risk of infection. Some women may find the vaginal assessment uncomfortable or embarrassing. There may also be minor discomfort similar to other vaginal examinations. Any adverse events or unexpected symptoms will be recorded by the research team.
-Participants can withdraw from the study at any time without giving a reason. Their decision will not affect their usual medical care or legal rights.

Where is the study run from?
The study is run from the Jessop Wing Maternity Unit at the Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Foundation Trust, in collaboration with the University of Sheffield (UK).

When does the study start and how long is it expected to run for?
January 2026 to December 2027.

Who is funding the study?
The study is funded by the Engineering and Physical Sciences Research Council (EPSRC) Healthcare Technologies Investigator-led Research scheme and the Yorkshire MedTech Place-Based Impact Accelerator Application Fund (UK).

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Polarisation-sensitive Optical Coherence Tomography (PS-OCT) for assessing cervical remodelling changes predictive of spontaneous human birth

Acronym
CervOScan

Study objectives
Three interrelated studies are proposed to address our aims and objectives.
Study A will recruit non-pregnant women who are undergoing a hysterectomy for a benign gynaecological condition who will donate their cervical tissue specimens for microscopic and spectroscopic structural studies.
Study B will be pregnant women attending ANC who will volunteer to participate in studies to assess the feasibility and accuracy of measuring cervical optical coherence tomography using a new device - the CervOScan.

The objectives include:
1. Determining the capacity of cervical PS-OCT to localise and quantify cervical collagen
2. Defining data collection protocols for pregnant women
3. Determining and selecting PS OCT quantitative parameters for defining cervical collagen distribution and density for future ML-enhanced predictive indices
4. Developing a research team for PPIE-supported grant applications for clinical studies

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/12/2025, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre Holland Drive, Newcastle Upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8010; sheffield.rec@hra.nhs.uk), ref: 25/YH/0249

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

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

Interventions
Study A: Correlating cervical tissue microscopy for collagen identification with PSOCT collagen birefringence assessment
In this ex vivo study, we will characterise the histological organisation of cervical collagen from non-pregnant hysterectomy cervical specimens and compare our findings with collagen assessment by the PSOCT device.
Ten non-pregnant women undergoing total abdominal hysterectomy (TAH) for benign reasons will be recruited. Immediately after surgical removal, a full-thickness wedge biopsy of the cervical tissue will be taken for histological examination and PSOCT assessment. Women will be identified and approached by research staff when they attend the preoperative assessment clinic several days before their scheduled operation. They will have been previously informed about the study by medical and nursing staff involved in their care, as well as through leaflets provided in the gynaecological and preoperative clinics. Since they will have been approached before admission for their surgery, potential participants will have had sufficient time to consider the study and decide whether to participate or not. Informed written consent will then be obtained from those women who choose to take part. The biopsy will be obtained after the surgeons have successfully removed the uterus with the cervix; PSOCT assessment will be conducted immediately, the tissue snapped frozen, and then transported to the laboratory for fixation and processing.

Study B: Repeatability and reproducibility of cervical PSOCT measurements
This initial clinical study will assess the feasibility, reproducibility, and acceptability of cervical PSOCT evaluation during pregnancy (between 20 and 28 weeks) for predicting the risk of preterm birth before 37 weeks and for determining cervical inducibility of labour at term in future studies.
Participants will include pregnant women attending antenatal clinics (n = 20). Over 200 of these women attend the Jessop Wing Preterm Birth Clinic (PTBC) annually.
We will ensure to approach all women accessing antenatal care at the Jessop Wing in Sheffield, including women from minority ethnic groups and those who do not speak English or do not have English as their first language. They will be informed about the study by medical and midwifery staff involved in their antenatal care, as well as through advert leaflets provided in the antenatal clinics. During recruitment, we will introduce and explain the study to them using the relevant hospital translation platform (Language Line Solutions UK) available, employing approved participant leaflets for the study. Prospective participants will have sufficient time to consider the study and decide whether to participate or not. Women who express interest in participating will then meet with a member of the research team, who will explain the study's aims and protocols in detail. Informed written consent will be obtained from those women who choose to take part.
Participants can withdraw from the study at any time after giving their consent. This will not affect the quality of care they receive. On all occasions, the investigator will ensure that the patient receives suitable follow-up at the clinic as needed.
Experimental procedure. Participants will be studied once between 20 and 28 weeks when they attend the antenatal clinic or preterm birth clinic.

Study C: Acceptability of cervical PS-OCT assessment
A subset of consenting participants in Study B will be scheduled for a qualitative assessment of the acceptability of cervical PSOCT during pregnancy (n = 10). We will adapt the interview prompts used in similar acceptability studies of previous devices, developed with input from past patients and maternity service users. A semi-structured interview approach will be employed. Interviews will be conducted within 2-4 weeks of the assessment. Participants can choose to have the interview via telephone or face-to-face. Key areas covered will include experiences of the intervention, comfort during the procedure, levels of anxiety and embarrassment, any unexpected symptoms afterwards, and motivations for participating.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cervical Polarisation Sensitive Optical Coherence Tomography (PS-OCT) Device (CervOScan)

Primary outcome(s)
1. The repeatability and reproducibility of measured cervical collagen birefringence between subjects and observers, measured using cervical OCT collagen birefringence measurement employing the CervOScan at between 20 and 28 weeks gestation

2. The acceptability of measuring cervical PS-OCT during pregnancy measured using a participant acceptability questionnaire and/or semi-structured interview exploring women’s experiences of the PS-OCT assessment, including comfort, anxiety, embarrassment, any unexpected symptoms afterwards, and motivations for participating at within 2–4 weeks after the cervical PS-OCT assessment, in a subset of pregnant participants from Study B

Key secondary outcome(s)

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Age >18 years, <55 years
Study A: Cervical tissue samples obtained from non-pregnant uterine specimens obtained at hysterectomy for benign non-cervical pathology (n = 10)
Study B: Feasibility/reproducibility studies of pregnant women at risk of preterm birth attending the antenatal clinics studied between 20 and 28 weeks gestation (n = 20)
Study C: Acceptability of cervical PS OCT during pregnancy (n=10, subset of Study B participants)

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Study A: Surgery for cervical pathology or suspected genital tract cancer

Study B:
1. Twin pregnancy
2. Inability to understand the study
3. Uncertain pregnancy duration
4. Established clinical vaginal infection
5. Current antibiotic treatment
6. Active vaginal bleeding
7. Ruptured fetal membranes

Date of first enrolment
02/03/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Hallamshire Hospital Sheffield
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Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Yorkshire MedTech

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available