ISRCTN17249451 https://doi.org/10.1186/ISRCTN17249451

Study to assess if sweat analysis from human finger tips can confirm breast cancer diagnosis

Submission date
26/07/2026

Recruitment status
Recruiting

Registration date
02/08/2026

Overall study status
Ongoing

Last Edited
25/09/2026

Condition category
Cancer

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

Plain English summary of protocol

Each year approximately 55,000 new cases of breast cancer are diagnosed in the UK, making it the most common cancer in British women1. Globally, it is estimated to affect over 1.7 million women and cause over 500 000 deaths each year.

Mammography is the gold standard for diagnostic imaging and screening, whereas biopsies confirm the diagnosis and allow assessment of tumour biology. Advanced (metastatic) disease is usually diagnosed, and monitored, with serial CT scans. A core biopsy, at new or metastatic diagnosis, is often performed to confirm and characterise disease biology. Whilst effective, these diagnostic tests are not perfect and carry a risk of harm. These may include exposure of individuals to radiation (mammogram, CT), limitations to their sensitivity and specificity (mammograms, CT), may cause pain and anxiety (mammogram, core biopsy) and carry a risk of bleeding (core biopsy). Some women find exposure of their breasts for mammography culturally unacceptable and decline screening or delay symptomatic presentation as a result. Therefore, there is the need for further technological developments for non-invasive and rapid tests for screening, diagnostic and monitoring purposes.

The project intends to evaluate the role of mass spectrometry of sweat derived from fingertip smears in the screening, diagnosis and monitoring of breast cancer. The technique will analyse fingertip sweat secretions from patients with and without breast cancer to attempt to detect a specific pattern of cancer markers to enable the identification of healthy versus patients with known breast cancer. Matrix Assisted Laser Desorption Ionisation Mass Spectrometry (MALDI MS) will be employed to recover cancer signatures, assisted by machine learning to discriminate between women with breast cancer versus those without and thus determine the specificity and sensitivity of this technique. We will also seek feedback from women who take part in the study, by means of a brief questionnaire, about the acceptability of the test. Lastly we will seek the opinions of health care professionals in the field of breast care, by means of qualitative interviews, relating to the feasibility of widespread application of the test in the NHS. We will also explore the barriers and facilitators to its adoption. It is hoped that by these 3 means we will be able to establish whether the test is accurate, effective, practical and acceptable, and thereby set the scene for a larger clinical trial.

The study will recruit approximately 200 patients, 80 with advanced breast cancer, 80 with newly diagnosed breast cancer and 40 healthy controls from breast clinics in Doncaster, which sees between 450 and 500 new cancers per year. Women will be invited to give 20 fingertip smears, three from each finger, after cleaning their fingers and then waiting for 15 minutes for fresh

secretions to re-form. The smears are completely painless and just involve gently pressing the fingertips onto a specially made aluminium slide. The process takes about 20 minutes altogether. Samples will then be transferred in dry ice to the Mass Spectrometry laboratory at Sheffield Hallam University for analysis. A set of pseudo-anonymised patient data about their cancer characteristics will also be collected to allow data interpretation. Women will also be asked to complete a brief questionnaire about the new test and whether they found it easy to understand and perform, acceptable, and not associated with any pain or distress.
This is a follow-on study of a previous MRC Confidence in Concept funded 'proof of concept' study, to validate our previous findings. This previous study, which ran between 2018 and 2020, recruited 200 women over a 5 month period from Doncaster Breast clinics. Uptake was in excess of 90% due to the very low burden of study participation. Our initial findings were ground-breaking, showing sensitivity and specificity of ~ 98%, leading to the prospect of establishing a new reliable, cost effective, non invasive test for breast cancer. We now need to validate these findings on a second cohort before seeking a much larger grant to take this to clinical application across the NHS. This project will therefore recruit a further cohort of 200 patients, undertake further development and refinements of the laboratory assay, attempt to replicate our previous laboratory findings (test sensitivity and specificity) and assess patient and health care professional opinions about wider use.

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Prof Lynda Wyld

ORCID ID
https://orcid.org/0000-0002-4046-5940

Contact details
Medical School, Beech Hill Road
Beech Hill Road
Sheffield
United Kingdom
S10 2RX
+44 1302642397
l.wyld@sheffield.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
364664

Central Portfolio Management System (CPMS)
71079

Study information

Scientific Title

Fingertip smear screening for breast cancer

Study objectives
1. To recruit a new cohort of women with and without breast cancer for fingertip smear sampling
2. To undertake further development work on the MALDI-MS assay to improve accuracy, reliability and reproducibility
3. To determine the sensitivity and specificity of the assay for the detection of breast cancer
4. To determine whether the assay can discriminate women with small-volume breast cancer from those with large-volume disease, and to establish thresholds for detection to better understand its clinical applications
5. To determine the ease of use and acceptability of the assay to women who have taken part in the study through a brief survey
6. To determine the views of healthcare professionals regarding the assay, including whether it could be used in place of, or alongside, existing technology, and to identify any barriers or facilitators to its widespread adoption within the NHS

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/05/2026, Tyne and Wear South Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle, NE2 4NQ, United Kingdom; +44 207 104 8014; tyneandwearsouth.rec@hra.nhs.uk), ref: 26/NE/0023

Primary study design
Observational

Secondary study design
Diagnostic exploratory study

Study type(s)

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Analysis of sweat from fingertip secretions using MALDI mass spectrometry to determine if it can differentiate between women with or without beast cancer, or quantify the burden of disease in women with breast cancer.

Following consent, participants will be asked to wash their hands with soap and water and refrain from touching any surfaces for 15 minutes. Three fingertip smear samples will then be collected from each of six fingertips (18 samples in total). Sample collection will be performed by gently pressing and swiping each fingertip onto a metal slide to transfer skin surface secretions. The procedure is designed to collect skin secretions only and does not involve the collection of biometric fingerprint data.

No additional clinical tests, investigations, or treatments beyond those required for routine medical care will be performed as part of the study. Collected samples will be stored for up to 15 years to enable future analyses as the analytical technology is further developed and refined.

For an ISRCTN registration, this would typically be described under "Intervention", "Study procedures" or "Participant timeline" in a concise, objective format:

Potentially eligible patients will be identified during routine clinical care and provided with verbal and written information about the study by a clinician or research nurse. Individuals will be given sufficient time to consider participation and discuss any questions with the study team before deciding whether to participate. Written informed consent will be obtained by trained research staff before any study-specific procedures are undertaken. Consent may be obtained either during the initial hospital visit or at a subsequent routine clinical appointment.

Following informed consent, participants will be asked to wash their hands with soap and water and avoid touching any surfaces for 15 minutes. Three fingertip smear samples will then be collected from each of six fingertips (18 samples in total) by gently pressing and swiping the fingertips onto a metal collection slide. The procedure is designed to collect skin surface secretions and does not involve the collection of biometric fingerprint data.

No additional clinical investigations, treatments, or procedures beyond those undertaken as part of routine medical care will be required for study participation. Collected samples will be stored for up to 15 years to facilitate future research and analysis as the technology undergoes further development and validation.

Research findings generated from stored samples will not routinely be returned to participants. As the assay is investigational and has not been validated for clinical use, individual test results will not be used to inform diagnosis, treatment decisions, or clinical management.

At the time of sample collection, research staff will record relevant demographic and clinical information, including age, sex, ethnicity, cancer diagnosis, breast cancer subtype, disease location, treatment history, and relevant family medical history. Samples and associated clinical data will be pseudonymised prior to transfer for research purposes. Laboratory researchers will have access only to de-identified samples and data and will not be able to identify individual participants.

Participants will also be invited to complete an optional brief acceptability questionnaire assessing the usability and acceptability of the fingertip sampling procedure, including ease of use and clarity of instructions. The questionnaire may be completed at the study visit or returned subsequently by post. Participation in the questionnaire component is voluntary and is not required for participation in the main study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MALDI Mass spetrometry

Primary outcome(s)

1. Diagnostic accuracy (sensitivity and specificity) measured using percentage of patients with cancer in whom cancer is diagnosed with the test at baseline at the time of cancer diagnosis for newly diagnosed early or advanced breast cancer or on clinic attendance if a health control, with non breast cancer diagnosis

Key secondary outcome(s)

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Breast cancer (either early or late stage) or healthy women attending breast clinic with benign pathology

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Subject has been diagnosed with any other type of cancers
2. Subject is currently undergoing active chemotherapy
3. Subject is pregnant or breast feeding

Date of first enrolment
01/10/2026

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

Sponsor information

Organisation
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/01yc93g67

Funder(s)

Funder type

Funder Name
Sheffield Hallam University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available