

Breast cancer early detection - is it feasible to use breast milk as a liquid biopsy to detect breast cancer?

Submission date 30/07/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/08/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 25/09/2026	Condition category Pregnancy and Childbirth	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Pregnancy related breast cancer (PRBC) is breast cancer diagnosed during pregnancy and postpartum breast cancer (PPBC) is breast cancer diagnosed within ten years after having a baby. Both PRBC and PPBC are associated with poor survival outcomes. Early detection of PRBC /PPBC in very high risk women is difficult and relies on cessation of breastfeeding to resume mammographic screening, despite continued breastfeeding lowering breast cancer risk.

This study is intended to investigate whether breast milk samples could be used in the future to detect early breast cancer, particularly in women high-risk for breast cancer. To do this we need to establish the best way to collect, transport and test breast milk in the laboratory. We are also investigating how acceptable this research is to the women who are involved.

Who can participate?

Women who are breastfeeding/expressing breast milk and at least 14 days postpartum.

What does the study involve?

Participants will provide a breast milk sample (aiming for 20ml per breast) and a blood sample (approximately 10ml).

Baseline data collection will include age, previous breast cancer history and pathology details (if applicable), age of baby, number of previous children, any breast abnormalities noticed and details of related referrals, comorbidities and confirmation of BC risk using Tyrer-Cuzick model. Participants will complete a brief questionnaire and structured interview which will be audio recorded.

Five participants will be offered a repeat study visit to repeat milk and blood samples collection and questionnaire/interview 8 weeks later.

Follow up will be for ten years, checking participant NHS number against a national cancer registry.

What are the possible benefits and risks of participating?

This study hopes to provide pilot data for further research using this innovative non-invasive method and establish the first protocol for breast milk as a liquid biopsy.

Risks to participants include:

Potential discomfort/bleeding from the blood test.

Possibility of psychological distress and cancer-related anxiety related to being investigated for cancer despite being well and not being high risk for breast cancer or possibly being informed of a higher lifetime risk of breast cancer than expected. We will monitor for any psychological impact during our structured interviews at each appointment, and advice will be given on reducing breast cancer risk in the future with lifestyle interventions.

Very low possibility that samples given may seem suspicious for cancer. If this happens contact will be made to discuss further and if necessary a referral will be made for further investigations including examination and potentially a breast scan and biopsy. This process may cause anxiety and distress.

Where is the study run from?

Manchester University NHS Foundation Trust

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

June 2026 to June 2037.

Who is funding the study?

1. The Academy of Medical Sciences Starter Grant
2. Prevent Breast Cancer
3. Paterson Project Awards from The Christie 2030 Research Programme

Who is the main contact?

Nicola Flaum, nicola.flaum@manchester.ac.uk

Contact information

Type(s)

Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)

341900

Central Portfolio Management System (CPMS)

70508

Protocol number

NHS002202

Study information

Scientific Title

Breast cancer early detection - breast milk (BRACELET-BM1): a feasibility study

Acronym

BRACELET-BM1

Study objectives**Primary Question/Objective**

- To define preliminary sensitivity of cfDNA detection from BM in women with BC.

Secondary Question/Objective:

- To determine the feasibility of collecting and analysing paired breast milk (BM) and blood samples for BC early detection in the general population and those at Very High Risk (VHR).
- To develop a register of women in the Greater Manchester VHR Breast Screening Programme (VHRBSP) who become pregnant or are breastfeeding.
- To assess acceptability of use of BM for BC early detection in terms of cancer-related worry, impact on psychological distress, and breastfeeding behaviour.
- To further engage the diverse community to enhance understanding and participation.
- To investigate novel DNA methylation signatures of cfDNA in BM samples.
- Build a breast biofluid biobank to form the basis for future studies.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 16/09/2025, South Central - Oxford A Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8241; oxford.rec@hra.nhs.uk), ref: 25/SC/0308

Primary study design

Observational

Secondary study design

Feasibility study

Study type(s)

Health condition(s) or problem(s) studied

Early detection of breast cancer in women who are breastfeeding.

Interventions

Breast cancer early detection - study to define preliminary sensitivity of cfDNA from breast milk in women with breast cancer and determine the feasibility of collecting and analysing paired breast milk and blood samples for breast cancer early detection in the general population and those at very high risk (VHR) for breast cancer. VHR women are those with a 30% or greater chance of developing breast cancer in their lifetime, for example, BRCA carriers.

Participants

40 lactating women:

- ≥14 days postpartum
- General-population level BC risk (25 women), VHR for BC (10 women) or with a history or diagnosis of breast cancer (5 women)

Study Intervention and/or Procedures

Overall protocol process:

- Advertisement placed at St Mary's Hospital antenatal department and local breastfeeding groups through social media
- Women VHR or with a history/diagnosis of breast cancer will be identified by clinical staff at local Family History Clinics (the Nightingale Centre)
- Information on study given
- If happy to participate they will give written consent, undergo BM collection and answer a brief questionnaire following regarding the acceptability of the procedure.
- Data collection at baseline (age, previous BC and pathology details, date of collection, age of baby, number of previous children, any breast abnormalities noticed and details of related referrals, comorbidities) and confirmation of BC risk using Tyrer-Cuzick model.
- Breast milk collected using a provided hospital grade breast pump (aiming for at least 20ml – approximately four teaspoons) and paired blood sample taken (10ml - approx. two teaspoon).
- Questionnaire and structured interview will be conducted by Dr Niki Flaum or a trained Research Practitioner. The interviews will be recorded at St Mary's Hospital or the Nightingale Centre at Wythenshawe Hospital at the study visit on a University of Manchester-approved Dictaphone and transcribed using a University-approved transcription service (1st Class Secretarial). This will be organised using NVivo software and analysed using a manifest-level

approach to reflexive thematic analysis.

- Samples will be sent from collection at study visit in St Mary's hospital or the Nightingale Centre by courier to the National Biomarker Centre
- Five participants will be offered a repeat study visit to repeat milk and blood samples collection and questionnaire/interview 8 weeks later.
- Breast milk and plasma samples will be stored initially in the National Biomarker Centre during the analysis process then long-term in Manchester Cancer Research Centre Biobank. A valid HTA Licence will be in place.
- As this process is experimental participants' results will not be fed back to them routinely.
- Follow up will be to two years via checking participant NHS number against a national cancer registry.
- Sequencing data will be processed and analysed with an in-house pipeline as previously published (<https://github.com/cruk-mi/mesa>). Fragmentomics features will be characterized with a set of software developed by the Mouliere lab (<https://github.com/mouliere-lab/FrEIA>), and nucleosome densities estimated via GRIFFIN (<https://github.com/adoebley/Griffin>). Mutations will be analysed via a standardised pipeline derived from MUTECT2.

Intervention Type

Other

Primary outcome(s)

1. Preliminary sensitivity of cell-free DNA (cfDNA) detection measured using quantitative PCR (qPCR) and Agilent TapeStation system, at baseline for all participants (a single sample), with 5 participants to return at the 8-week timepoint for repeat samples

Key secondary outcome(s)

1. Acceptability of use of BM for BC early detection in terms of cancer-related worry, impact on psychological distress, and breastfeeding behaviour, measured using questionnaires (sections include mental well-being, attitudes toward breast cancer screening using breast milk, experience of breastfeeding) at baseline and 8-weeks

Completion date

30/06/2037

Eligibility

Key inclusion criteria

1. Women breastfeeding/expressing breast milk
2. ≥ 14 days postpartum
3. General-population level BC risk, very high risk (VHR) for BC or with a history or diagnosis of breast cancer

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. Refusal or inability to give informed consent
2. Any acute or chronic condition that would limit the ability of the participant to take part in the study

Date of first enrolment

22/06/2026

Date of final enrolment

30/06/2027

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

St Marys Hospital, Manchester University NHS Foundation Trust

St Marys Hospital

Manchester Royal Infirmary

Oxford Road

Manchester

England

M13 9WL

Study participating centre

Nightingale Centre, Manchester University NHS Foundation Trust

Nightingale Centre

Wythenshawe Hospital

Southmoor Road

Wythenshawe

Manchester

England

M23 9LT

Sponsor information

Organisation

University of Manchester

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Funder Name

Academy of Medical Sciences

Alternative Name(s)

The Academy of Medical Sciences

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

Prevent Breast Cancer

Funder Name

Christie Charity

Alternative Name(s)

Christie Charitable Fund

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available