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A study for the future development of an early-stage breast cancer detection test

Submission date
25/02/2026

Recruitment status
Recruiting

Registration date
28/05/2026

Overall study status
Ongoing

Last Edited
05/11/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Breast cancer is one of the most common cancers in women, but many cases are only found at a late stage when treatment is harder. The NHS breast screening programme only offers mammograms to women aged 30–70, leaving millions of women without regular checks. A company called Faster Diagnostics Ltd is developing a new blood test — called the Artemis Test™ — that could detect breast cancer at a very early stage, without radiation and without the need for a mammogram. This study (called FAST 40) is a small proof-of-concept study to test whether patterns in blood plasma can reliably tell apart women who have early breast cancer from those who do not. If successful, the findings will help develop the Artemis Test™ into a full triage tool in the future.

Who can participate?
The study is looking to recruit 120 women in total, aged between 30 and 71 years old. Half of these (60 women) will be healthy volunteers with no breast cancer diagnosis. The other half (60 women) will be patients who have recently been diagnosed with early-stage breast cancer (Stage 0 to Stage IV) and have not yet started treatment. Participants must be female, within the stated age range, and willing to give a single blood sample. Women who are pregnant, or who have had breast cancer treatment already, will not be eligible to take part.

What does the study involve?
Taking part involves just one visit to a GP surgery. At that visit, a member of the study team will explain the study in full and ask for written consent. A small blood sample will then be taken by a trained professional — this is the same as a routine blood test. Participants will also be asked a few questions about their general health, any other medical conditions, smoking history, and what they ate or drank in the three hours before the blood draw. For breast cancer patients, a copy of their pathology report will also be noted. The blood sample will be sent to two specialist laboratories — the National Physical Laboratory in London and the University of Leicester — where it will be analysed using advanced scientific tests. Participants will receive a payment of £50 for completing their study visit.

What are the possible benefits and risks of participating?
There is no direct medical benefit to participants from taking part in this study, as the test is still

in development and cannot tell individuals whether they have cancer or not. However, the data collected could help develop a new blood test that may in future benefit many women by detecting breast cancer earlier. The risks of taking part are very low. The only physical procedure involved is a standard blood draw, which carries the same minor risks as any routine blood test — such as slight bruising or soreness around the needle site. The study has been classed as Type A, meaning it carries no greater risk than standard medical care.

Where is the study run from?
The study will be run at NHS GP surgery sites across the UK. The study is being managed day-to-day by PHARMExcel Ltd, a Contract Research Organisation (CRO) based in the United Kingdom, on behalf of Faster Diagnostics Ltd. Blood samples will be analysed at two specialist sites: the National Physical Laboratory (NPL) in London and the University of Leicester.

When is the study starting and how long is it expected to run for?
March 2026 to March 2027

Who is funding the study?
Faster Diagnostics Ltd, the company that is developing the Artemis Test™.

Who is the main contact?
info@fasterdiagnostics.com

Contact information

Type(s)
Scientific, Public

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Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
368310

Study information

Scientific Title
A non-interventional, proof of concept study to collect blood samples from patients with stage 0-IV breast cancer and from healthy participants to measure plasma biomarkers for future development of an early-stage breast cancer detection test

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/05/2026, HRA (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; approvals@hra.hns.uk), ref: 26/EM/0090

Primary study design
Observational

Secondary study design
Case-control study

Study type(s)

Health condition(s) or problem(s) studied
Stage 0-IV breast cancer

Interventions
Current methodology as of 05/11/2026:
This study is non-interventional and will be conducted at primary care GP NHS sites in the UK only.

Screening procedures include informed consent, a review of participant medical history, smoking history, concomitant medication, HIV/HBV/HCV testing, eligibility assessment and phlebotomy where participants will provide a single blood sample. All study procedures will be undertaken in a single visit to the GP surgery.

In Part A, 20 breast cancer participants will be recruited with Stage 0-II breast cancer, and 20 controls.
In Part B, 40 breast cancer participants will be recruited with Stage 0-IV breast cancer, and 40 age-matched healthy controls.

The target recruitment in Part A will be as follows:

1. 10 participants aged 30-40 years:
5 breast cancer patients
5 controls

2. 10 participants aged 41-50 years:
5 breast cancer patients
5 controls

3. 10 participants aged 51-60 years:
5 breast cancer patients
5 controls

4. 10 participants aged 61-71 years:
5 breast cancer patients
5 controls

Sites will recruit the same number of breast cancer participants and controls in each of the two groups and each site will be assigned an anticipated recruitment target and a maximum enrolment cap.

The target recruitment of breast cancer participants in Part B will be as follows:
Stage 0: 4 breast cancer participants
Stage I: 14 breast cancer participants
Stage II: 12 breast cancer participants
Stage III: 6 breast cancer participants
Stage IV: 4 breast cancer participants

Healthy controls will be age-matched to the breast cancer participants within the following age groups: 30–40, 41–50, 51–60, and 61–71 years.

A summary of the total data that will be collected is below:
1. One blood sample
2. Detail of the food and drink participants have consumed prior to the blood draw
3. Age
4. Gender
5. Smoking history
6. Pathology report (breast cancer donors only)
7. Cancer grade (breast cancer donors only)
8. Any other medical conditions participants' may have
9. Treatment notes

Blood samples will then be sent to the National Physics Laboratory (NPL) and Leicester University for analysis.

Previous methodology:
This study is non-interventional and will be conducted at primary care GP NHS sites in the UK only.

Screening procedures include informed consent, a review of participant medical history, smoking history, concomitant medication, HIV/HBV/HCV testing, eligibility assessment and phlebotomy where participants will provide a single blood sample. All study procedures will be undertaken in a single visit to the GP surgery.

Participants will then be enrolled into one of two age stratified groups:

20 participants aged 50-60 years:
10 breast cancer patients
10 controls

20 participants aged 60-71 years:
10 breast cancer patients
10 controls

Sites will recruit the same number of breast cancer participants and controls in each of the two groups and each site will be assigned an anticipated recruitment target and a maximum enrolment cap.

A summary of the total data that will be collected is below:
1. One blood sample
2. Detail of the food and drink participants have consumed prior to the blood draw
3. Age
4. Gender
5. Smoking history
6. Pathology report (breast cancer donors only)
7. Cancer grade (breast cancer donors only)
8. Any other medical conditions participants' may have
9. Treatment notes

Blood samples will then be sent to the National Physics Laboratory (NPL) and Leicester University for analysis.

Intervention Type
Other

Primary outcome(s)
1. Metabolites in plasma measured using mass spectrometry at baseline

2. Genomics measured using next generation sequencing at baseline

Key secondary outcome(s)

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/11/2026:
Breast cancer participants group:
1. Females aged ≥30 years to ≤71 years of age, inclusive at time of consent
2. Breast cancer participants: diagnosed with breast cancer stage 0 to IV post biopsy and mammogram screening
3. Breast cancer participants: treatment naïve participants only, diagnosed by biopsy and

mammogram
4. Breast cancer participants: primary cancer donors only

Healthy participants group:
1. Females aged ≥30 years to ≤71 years of age, inclusive at time of consent
2. Healthy volunteer participants: no current or prior diagnosis of any cancer
3. Healthy volunteer participants: not currently under investigation for any suspected malignancy
4. Healthy volunteer participants: no current symptoms suggestive of breast pathology (e.g., palpable lump, nipple discharge, skin changes)

Previous inclusion criteria:
Breast cancer participants group:
1. Females aged ≥50 years to ≤71 years of age, inclusive at time of consent
2.Breast cancer participants: diagnosed with breast cancer stage 0 to II post biopsy and mammogram screening
3. Breast cancer participants: treatment naïve participants only, diagnosed by biopsy and mammogram
4. Breast cancer participants: primary cancer donors only

Healthy participants group:
1. Females aged ≥50 years to ≤71 years of age, inclusive at time of consent
2. Healthy volunteer participants: no current or prior diagnosis of any cancer
3. Healthy volunteer participants: not currently under investigation for any suspected malignancy
4. Healthy volunteer participants: no current symptoms suggestive of breast pathology (e.g., palpable lump, nipple discharge, skin changes)

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
30 Years

Upper age limit
71 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 05/11/2026:
1. HIV/HBV/HCV positive, as determined by rapid strip test
2. Women who are pregnant, or lactating
3. Recent receipt of a vaccine within 90 days or five half-lives, whichever is longer or receipt of an influenza vaccine within 21 days prior to screening.
4. Participants in receipt of HRT within the last 90 days (including patches, pessaries, coil and

tablets).
5. Participation in another clinical study investigating a vaccine, drug, medical device, or medical procedure within 90 days or five half-lives, whichever is longer, prior to consent or planned participation in such a study during the period of this clinical study
6. Receipt of immunoglobulins, blood or blood-derived products within 90 days prior to consent
7. Chronic illness that, in the opinion of the investigator, is at a stage where it might interfere with study conduct or study completion
8. Current alcohol abuse or drug addiction (reported or suspected)
9. Identified as an Investigator or employee of the Investigator or study centercentre with direct involvement in the proposed study, or identified as an immediate family member (i.e., parent, spouse, natural or adopted child) of the Investigator or employee with direct involvement in the proposed study. (i.e., in the employment of the clinical study sites)
10. Participants receiving any of the following medications:
10.1. Thyroid Replacement Therapy: Levothyroxine sodium for the management of hypothyroidism
10.2. Metformin for glycaemic control
10.3. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), including, but not limited to, Ibuprofen or Naproxen within 14 days
11. Participants with a known diagnosis of Type 1 or Type 2 diabetes mellitus

Previous exclusion criteria:
1. HIV/HBV/HCV positive, as determined by rapid strip test
2. Women who are pregnant, or lactating
3. Recent receipt of a vaccine within 90 days or five half-lives, whichever is longer
4. Participants in receipt of HRT
5. Participation in another clinical study investigating a vaccine, drug, medical device, or medical procedure within 90 days or five half-lives, whichever is longer, prior to consent or planned participation in such a study during the period of this clinical study
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10. Participants receiving any of the following medications:
10.1. Thyroid Replacement Therapy: Levothyroxine sodium for the management of hypothyroidism
10.2. Metformin for glycaemic control
10.3. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), including, but not limited to, Ibuprofen or Naproxen

Date of first enrolment
13/04/2026

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Research Link
Old School Surgery, 2A Station St, Kibworth Beauchamp
Leicester
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Study participating centre
Marine Lake Medical Practice
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Sponsor information

Organisation
Faster dignostics Ltd

Funder(s)

Funder type

Funder Name
Faster diagnostics Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5.0		05/11/2026	No	No