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Earlier detection of breast cancer using a blood test and Raman spectroscopy

Submission date
04/07/2023

Recruitment status
No longer recruiting

Registration date
24/08/2023

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Breast cancer is the most common cancer in the UK. 15 out of 100 newly diagnosed cancers in the UK are breast cancers. Survival for breast cancer is generally good, especially if a patient is diagnosed early. The benefits of finding breast cancer early are clear and often result in requiring less treatment with a greater likelihood of cure. Symptoms of breast cancer include a lump that can be felt, skin/nipple changes and nipple discharge. If patients already have symptoms, they are usually referred to a one-stop breast clinic. This is where a patient will have the gold standard investigation which includes several tests known as 'triple assessment'. Patients will have an examination of their breasts alongside imaging (x-ray mammogram or ultrasound), and a tissue sample (biopsy) is taken if these tests reveal an abnormal area. The aim of this project is to develop a blood test that can detect breast cancer cells, and also the type of breast cancer earlier than we can at present. Raman spectroscopy uses a laser to excite the chemical signals in a blood sample to create a fingerprint of that sample. If breast cancer features are present, the breast cancer fingerprint can then be analysed to provide information on treatment strategy. Ultimately, this technique would allow earlier diagnosis and may help patients to start treatment sooner than is possible currently. The addition of a cancer-specific test such as Raman to the urgent suspected breast cancer referral pathways could increase the probability of breast cancer being confirmed in patients who are referred to clinics. This could assist with more effective triage of patients to breast clinics, particularly with current levels of high demand.

Who can participate?
Women aged over 18 years old with a confirmed diagnosis of breast cancer and a control group of women with a benign outcome after assessment from a specialist breast triple assessment clinic

What does the study involve?
This study will recruit symptomatic patients who are referred to specialist breast services with suspicion of breast cancer. The study seeks to obtain blood samples for analysis using spectroscopy in vitro diagnostic devices. Outcomes from specialist breast clinics (cancer/normal assessment findings) will be used to train and test a machine learning algorithm to allow calculation of the sensitivity and specificity of the device.

What are the possible benefits and risks of participating?
This research will investigate if the cause of a breast lump (including cancer) can be diagnosed by a simple blood test. Early diagnosis before symptoms develop is vital for the best outcome. Current screening tests can be invasive and unpleasant, so alternative tests are needed. There is potential for patient benefit from this original research, which includes easier detection by a blood test and the ability to monitor response to treatment. There are small risks involved with taking a blood sample. These include bruising, bleeding, pain/discomfort and infection at the local site from which the blood is taken.

Where is the study run from?
Swansea Bay University Health Board (UK)

When is the study starting and how long is it expected to run for?
August 2022 to August 2024

Who is funding the study?
Cancer Research Wales (UK)

Who is the main contact?
Prof Dean Harris, dean.a.harris@wales.nhs.uk (UK)

Contact information

Type(s)
Principal investigator

Contact name
Prof Dean Harris

ORCID ID
https://orcid.org/0000-0003-2673-8946

Contact details
Swansea Bay University Health Board
1 Talbot Gateway
Baglan Energy Park
Baglan
Port Talbot
Swansea
United Kingdom
SA12 7BR
+44 (0)1792285459
dean.a.harris@wales.nhs.uk

Type(s)
Scientific

Contact name
Mr Imran Mohamed

ORCID ID
https://orcid.org/0000-0003-3831-8594

Contact details
Swansea Bay University Health Board
1 Talbot Gateway
Baglan Energy Park
Baglan
Port Talbot
Swansea
United Kingdom
SA12 7BR
+44 (0)1792 285459
imran.mohamed@wales.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
319524

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 319524, CPMS 56288

Study information

Scientific Title
Prospective multi-site observational cohort study of serum Raman spectroscopy and supervised machine learning in the detection of breast cancer

Acronym
BrCa-SPECT

Study objectives
The aim of this project is to develop a blood test that can detect breast cancer cells, and also the type of breast cancer earlier than we can at present. Raman spectroscopy uses a laser to excite the chemical signals in a blood sample to create a fingerprint of that sample. If breast cancer features are present, the breast cancer fingerprint can then be analysed to provide information on treatment strategy. Ultimately, this technique would allow earlier diagnosis and may help patients to start treatment sooner than is possible currently.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 15/05/2023, South West - Cornwall & Plymouth Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)2071048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 23/SW/0046

Study design
Prospective multi-site observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
The study involves taking a blood test (approximately one tablespoon of blood) for analysis. Participants will be asked to participate in the study by signing and initialling a consent form. The blood test can then be collected by a researcher experienced in blood sampling. Participants will be required to fast before the blood test is taken (i.e. no food and only clear fluids for up to 4 hours before the blood test). There is no further action needed by participants. The results from the blood test will not affect clinical care as it is a research tool only.

The primary outcome will establish the performance of the Raman spectroscopy analysis system for the detection of breast neoplasia (1. Ductal carcinoma-in-situ and 2. Invasive carcinoma) in its intended population (symptomatic patients referred to tertiary breast services undergoing triple assessment) through outcome measures of test sensitivity and specificity.

Intervention Type
Not Specified

Primary outcome(s)
Test sensitivity and specificity measured using outcomes from specialist breast clinics (cancer /normal assessment findings) to train and test a machine learning algorithm at one timepoint

Key secondary outcome(s))
1. To determine an association between modes of presentation/symptomatology of breast cancer measured using Raman spectroscopy at one timepoint
2. To determine an association between breast cancer / pre-malignant conditions (DCIS) measured using Raman spectroscopy at one timepoint

Completion date
31/08/2024

Eligibility

Key inclusion criteria
1. Aged 18 years old or over
2. Confirmed histopathological diagnosis of breast cancer OR benign outcome after assessment

from specialist breast triple assessment clinic (control group)
3. Willing to provide informed consent for study participation
4. Able and willing to provide blood serum samples

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Male sex (majority of patients with breast cancer are female and the study is unlikely to recruit a sufficient number of male patients to provide a representative sample that could be compared between sexes)
2. Under the age of 18 years old
3. Unwilling/unable to consent to trial participation

Patients from vulnerable groups (defined as lacking capacity to freely give informed consent)

Unwilling/unable to provide blood samples required for the study.

Date of first enrolment
01/11/2023

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Swansea Bay University Health Board
1 Talbot Gateway
Baglan Energy Park
Baglan
Port Talbot

Swansea
United Kingdom
SA12 7BR

Study participating centre
The Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
United Kingdom
CF72 8XR

Study participating centre
Nevill Hall Hospital
unknown
Abergavenny
United Kingdom
NP7 7EG

Sponsor information

Organisation
Swansea Bay University Health Board

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Research organisation

Funder Name
Cancer Research Wales

Alternative Name(s)
Ymchwil Canser Cymru, CRW

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be made available upon request from the Chief Investigator, Prof. Dean Harris (dean.a.harris@wales.nhs.uk). Informed consent from participants was required and obtained. Only pseudonymised data relevant to the study is shared with researchers. All identifiable data is held by their routine clinical care team/NHS research team recruiting the patient. Any identifiable data especially relating to medical records and genetic data will not be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes