Breast cancer biomarkers and treatment targets

Submission date 09/05/2011	Recruitment status No longer recruiting	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/09/2011	Completed	Results
Last Edited	Condition category	Individual participant data
03/03/2020	Cancer	Record updated in last year

Plain English summary of protocol

Background and study aims

Breast cancer is now the most common cancer in the United Kingdom. More than 45,500 women per year are now diagnosed with breast cancer and this continues to increase. However, new targeted treatments such as herceptin have led to successful therapies. This project aims to study and investigate new targets for treating breast cancer.

Who can participate?
Patients with breast cancer

What does the study involve?

This study observes and investigates extra samples of breast cancer tissue that is not required for diagnosing the patient, or tissue that already exists in a tumour bank. Patients will have received normal clinical care.

What are the possible benefits and risks of participating?

Benefits of the study are that new treatments may be developed for breast cancer. There are no known risks associated with this study as patients are not directly involved.

Where is the study run from? Southampton General Hospital (UK)

When is the study starting and how long is it expected to run for? November 2010 to October 2025

Who is funding the study? Cancer Research UK

Who is the main contact? Mr Ramsey Cutress r.i.cutress@soton.ac.uk

Contact information

Type(s)

Scientific

Contact name

Mr Ramsey Cutress

Contact details

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Additional identifiers

Protocol serial number

RHMCAN0738 (Protocol version 1.3)

Study information

Scientific Title

Breast cancer biomarkers translational research and validation study

Study objectives

The aim of this study is to identify, futher understand, validate and characterise breast cancer molecules and biomarkers with a view to designing novel molecular rational therapies for breast cancer.

The study is laboratory based using human tissue samples and is hypothesis generating rather than a definitive trial. We will explore the potential of candidate proteins as future biomarkers or therapeutic targets.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton and South West Hampshire Regional Ethics Committee, 09/11/2010, ref: 10/H0504 /73

Study design

Open-label non-randomised retrospective study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

The study is non-interventional and laboratory-based. This research is hypothesis-generating rather than a clinical trial.

Biomarker identification, validation and therapeutic targets.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Anticipated outcomes from this study are expression levels of candidate biomarkers in breast cancer. The expression levels will be evaluated by various means, but of this study is to determine the optimum methods of biomarker validation.

Validate BAG-1 as a bimomarker in breast cancer

Key secondary outcome(s))

Identify other proteins related to BAG-1 as possible biomarkers in breast cancer and therapeutic targets

Completion date

01/10/2025

Eligibility

Key inclusion criteria

All tissue will be obtained from pre-existing sources (tissue bank, archival material surplus to diagnostic requirements, tissue microarrays generated for research purpose). There will be no active patient participation.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

All tissue will be obtained from pre-existing sources (tissue bank, archival material surplus to diagnostic requirements, tissue microarrays generated for research purpose). There will be no active patient participation.

Date of first enrolment 10/11/2010

Date of final enrolment 01/10/2025

Locations

Countries of recruitment

United Kingdom

England

SO16 6YD

Study participating centre CRUK Centre Southampton United Kingdom

Sponsor information

Organisation

University Hospital Southampton (UK)

ROR

https://ror.org/0485axj58

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes