

# Breast cancer biomarkers and treatment targets

<b>Submission date</b> 09/05/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/03/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 biomarker 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

**Study participating centre**

**CRUK Centre**

Southampton

United Kingdom

SO16 6YD

**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