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Breast cancer biomarkers and treatment targets

Submission date 09/05/2011	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 21/09/2011	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 03/03/2020	**Condition category** Cancer	[ ] Individual participant data [ ] 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
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Contact information

Type(s)

Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient confidentiality will be maintained by removing patient identifiable labels other than an assigned study specific number to create linked anonymised samples. No personally identifying information will be realeased in any report or publication relating to this work.

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 measure
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

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

Overall study start date
10/11/2010

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

Age group
Adult

Sex
Female

Target number of participants
Over 500 samples are currently held in the tissue bank at present

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
England

United Kingdom

Study participating centre
CRUK Centre
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration