

Breakthrough Breast Cancer & Cancer Research UK Genetic Breast Cancer Trial

Submission date 10/05/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/06/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/02/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-carboplatin-or-docetaxel-chemotherapy-for-advanced-genetic-breast-cancer>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2004-001496-20

ClinicalTrials.gov (NCT)

NCT00321633

Protocol serial number

N/A

Study information

Scientific Title

Breakthrough Breast Cancer & Cancer Research UK Genetic Breast Cancer Trial

Acronym

BRCA Trial

Study objectives

Women who carry mutations in BRCA1 and 2 genes have an increased risk of up to 85% of developing breast cancer. Despite recent improvements in detection and treatment of early breast cancer, 25% of women will relapse with metastatic disease. Breast cancers in BRCA1 and 2 carriers are more frequently of high grade than cancers of women in general. Recent laboratory data have suggested that these mutations are sensitive to platinum drugs. The purpose of this trial is to assess whether carboplatin alone is a safe and effective treatment of metastatic breast cancer in women who are BRCA1 and 2 carriers. This will be compared to standard treatment with docetaxel in terms of toxicity, response and time to progression.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Health condition(s) or problem(s) studied

Metastatic genetic breast cancer

Interventions

Patients will be randomized 2:1 in favour of carboplatin.

Treatment one: Carboplatin equal to the Area Under the Curve (AUC) of 6 mg/mL per minute every three weeks for six cycles

Treatment two: Docetaxel 100 mg/m² every three weeks for six cycles

Computed Tomography (CT) scan after three cycles:

If no progression -continue with next three cycles

If progression cross over to other treatment

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Docetaxel, carboplatin

Primary outcome(s)

To determine whether carboplatin is a safe and effective treatment for women with relapsed breast cancer, who are BRCA 1 or 2 carriers.

Key secondary outcome(s)

To estimate progression free survival.

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Histologically confirmed metastatic breast cancer in BRCA 1/2 mutation carriers
2. Chemotherapy clinically indicated
3. Normal haematology and renal function
4. Patient consent
5. World Health Organisation (WHO) grade zero to two

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

Key exclusion criteria

1. Unfit for chemotherapy or neuropathy more than Grade one
2. Known allergy to/previous treatment with platinum compounds
3. Known sensitivity to taxanes
4. Abnormal serum bilirubin
5. Life expectancy less than three months
6. Previous malignancies, uncontrolled medical conditions or concurrent illness
7. Pregnant or lactating women

Date of first enrolment

01/01/2005

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

North East Thames Clinical Genetics Service

London

United Kingdom

WC1 1EH

Sponsor information

Organisation

University College London (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Breakthrough Breast Cancer

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

Cancer Research UK (via CTAAC)

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