Breakthrough Breast Cancer & Cancer Research UK Genetic Breast Cancer Trial

Submission date	Recruitment status	[X] Prospectively registered
10/05/2004	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
22/06/2004	Stopped	Results
Last Edited	Condition category	[] Individual participant data
14/02/2019	Cancer	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

Dr James Mackay

Contact details

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Additional identifiers

EudraCT/CTIS number

2004-001496-20

IRAS number

ClinicalTrials.gov number

NCT00321633

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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/m^2 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 measure

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

Secondary outcome measures

To estimate progression free survival.

Overall study start date

01/01/2005

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

Age group

Not Specified

Sex

Female

Target number of participants

148

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

England

United Kingdom

Study participating centre North East Thames Clinical Genetics Service

London United Kingdom WC1 1EH

Sponsor information

Organisation

University College London (UK)

Sponsor details

Gower Street London England United Kingdom WC1E 6BT

Sponsor type

University/education

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, 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 summaryNot provided at time of registration