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Breakthrough Breast Cancer & Cancer Research UK Genetic Breast Cancer Trial

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

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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00321633

Clinical Trials Information System (CTIS)
2004-001496-20

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

Primary study design
Interventional

Study design
Randomised controlled trial

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/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(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