ISRCTN43372330 https://doi.org/10.1186/ISRCTN43372330

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

Contact name
Dr James Mackay

Contact details
North East Thames Clinical Genetics Service
Great Ormond Street Hospital & the Institute of Child Health
30 Guilford Street
London
United Kingdom
WC1 1EH

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 summary

Not provided at time of registration