ISRCTN77234840 https://doi.org/10.1186/ISRCTN77234840

# Neoadjuvant study of Chemotherapy versus EndocriNe Therapy in postmenopausal patients with primary breast cancer

**Submission date**
31/05/2006

**Recruitment status**
No longer recruiting

**Registration date**
13/07/2006

**Overall study status**
Completed

**Last Edited**
19/03/2020

**Condition category**
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
http://www.cancerhelp.org.uk/trials/a-trial-to-compare-chemotherapy-with-hormone-therapy-before-surgery-for-breast-cancer

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Charles R Coombes

**Contact details**
Faculty of Medicine
Imperial College London
Hammersmith Hospitals NHS Trust
8th Floor
MRC Cyclotron Building
Du Cane Road
London
United Kingdom
W12 0NN
+44 (0)20 8383 5828
c.coombes@imperial.ac.uk

## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00963729

**Clinical Trials Information System (CTIS)**
2006-003596-12

# Study information

### Scientific Title
Neoadjuvant study of Chemotherapy versus EndocriNe Therapy in postmenopausal patients with primary breast cancer

### Acronym
Neo-CENT

### Study objectives
Neoadjuvant chemotherapy is considered the standard of care in the management of locally advanced breast cancer but phase III trials involving third generation aromatase inhibitors have established both the efficacy of these agents in the neoadjuvant setting. However it is not known whether endocrine therapy is as effective in the neoadjuvant setting as neoadjuvant chemotherapy.

There are still many aspects of the pathways of cytoreduction triggered by both chemotherapy and endocrine therapy which are poorly characterized and a study such as this is a valuable opportunity to study these pathways in vivo. In addition, there are currently no reliable biomarkers which will predict for a given patient with estrogen-receptor positive breast cancer whether endocrine or chemotherapy will offer more effective downstaging. If it can be established that endocrine neoadjuvant chemotherapy is as effective as neoadjuvant chemotherapy for estrogen-receptor positive breast cancer, (or more likely a molecular subset thereof), then the result of an in vivo assay of hormone sensitivity in the form of degree of clinical and pathological response may help define a potentially large subset of patients currently receiving adjuvant chemotherapy without survival benefit.

Please note as of 08/02/2011 the overall trial end date has been extended from 31/12/2008 to 31/03/2011 and the target number of participants increased from 644 to 716.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Leeds (East) Research Ethics Committee on 23/01/2008 (ref: 07/H1306/164).

### Study design
Multi-centre randomised parallel-group comparative phase III trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Breast Cancer

### Interventions
Arm A: fluorouracil (5 FU) 600 mg/m2, epirubicin 75 mg/m2 and cyclophosphamide 600 mg/m2; six cycles every 21 days
Arm B: letrozole 2.5 mg po per day for 21 weeks

### Intervention Type
Drug

### Phase
Phase III

### Drug/device/biological/vaccine name(s)
Epirubicin, cyclophosphamide, fluorouracil and letrozole

### Primary outcome(s)
1. Clinical response rates

### Key secondary outcome(s))
1. Radiological response rates using breast ultrasound and mammogram
2. To compare the rates of conservation surgery

3. To compare degree of pathological response
4. To compare Ki-67 protein changes and its relationship to treatment response
5. To investigate the roles of members of the forkhead family in mediating endocrine and chemotherapy-induced regression
6. To evaluate the length of time to maximum response within the treatment period
7. To compare effects on markers of apoptosis and the cell cycle
8. To compare tolerability of the various treatments
9. To compare quality of life (QoL) of the various treatments

### Completion date
31/03/2011

## Eligibility

### Key inclusion criteria
1. Histologically proven primary breast cancer which is thought to require mastectomy and where it is felt that cytoreductive systemic therapy would enable conservative surgery to be performed.
2. Postmenopausal up to the age of 75 years of age
3. Estrogen-receptor positive
4. Pre-treatment haematology and biochemistry values within acceptable limits
5. World Health Organisation (WHO) performance status zero or one
6. Primary breast tumour amenable to biopsy
7. Consent to having a repeat biopsy of breast tumour
8. Written informed consent prior to commencement of specific protocol procedures

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
1. Indicated for urgent neoadjuvant therapy, i.e., inflammatory or near ulcerating breast cancer
2. Bilateral invasive breast cancer
3. Any prior chemotherapy, hormone therapy or radiation for breast cancer
4. Evidence of distant metastatic disease as disclosed by bone scan, liver ultrasound scan and chest radiology
5. Past or current history of neoplasm other than breast carcinoma, except for:
a. curatively treated non-melanoma skin cancer
b. in situ carcinoma of the cervix
c. other cancer curatively treated and with no evidence of disease for at least ten years
d. ipsilateral Ductal Carcinoma In-Situ (DCIS) of the breast
e. Lobular Carcinoma In-Situ (LCIS) of the breast
6. Other serious illness or medical condition:
a. congestive heart failure or unstable angina pectoris, previous history of myocardial infarction within one year from study entry, uncontrolled hypertension or high-risk uncontrolled arrhythmias
b. history of significant neurologic or psychiatric disorders including psychotic disorders, dementia or seizures that would prohibit the understanding and giving of informed consent
c. active uncontrolled infection
d. active peptic ulcer, unstable diabetes mellitus
7. In the opinion of the investigator, any evidence of severe or uncontrolled systemic disease such as unstable hypertension, respiratory, cardiac, hepatic, and renal disease

### Date of first enrolment
01/09/2006

### Date of final enrolment
31/03/2011

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre

**Imperial College London**
London
United Kingdom
W12 0NN

# Sponsor information

**Organisation**
Imperial College London (UK)

**ROR**
https://ror.org/041kmwe10

# Funder(s)

**Funder type**
Charity

**Funder Name**
Cancer Research UK (CRUK) (UK) (ref: C37/A9356)

**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

**Funder Name**
Novartis Pharmaceuticals (UK)

# Results and Publications

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2014 | | Yes | No |
| Plain English results | | | | No | Yes |