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

Submission date	Recruitment status	[X] Prospectively registered
31/05/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
13/07/2006	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
19/03/2020	Cancer	

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

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-003596-12

ClinicalTrials.gov (NCT)

NCT00963729

Protocol serial number

N/A

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

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