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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

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Additional identifiers

EudraCT/CTIS number
2006-003596-12

IRAS number

ClinicalTrials.gov number
NCT00963729

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
1. Clinical response rates

Secondary outcome measures
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

Overall study start date
01/09/2006

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

Age group
Adult

Sex
Female

Target number of participants
40 for feasibility study and 676 for main study (716 total)

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
England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Charing Cross Campus
Fulham Palace Road
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England
United Kingdom
W6 8RF

Sponsor type
University/education

Website
www.ic.ac.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, 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

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

Study outputs

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