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National breast cancer study of Epirubicin plus CMF versus classical CMF Adjuvant Therapy

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 25/01/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/national-breast-cancer-study-of-epirubicin-as-adjuvant-therapy

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003577

Secondary identifying numbers
BR3014

Study information

Scientific Title
National breast cancer study of Epirubicin plus CMF versus classical CMF Adjuvant Therapy

Acronym
NEAT

Study objectives
In women with early breast cancer, adjuvant combination chemotherapy which schedules 4 cycles of epirubicin, followed by 4 cycles of classical CMF, is significantly superior to classical CMF for 6 cycles, in terms of disease-free and overall survival.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
1. Group A: Chemotherapy, cyclophosphamide, methotrexate and 5-fluorouracil (CMF) repeated every 3 weeks for six cycles.
2. Group B: Chemotherapy, epirubicin repeated every 3 weeks for four cycles followed by CMF repeated every 3 weeks for four cycles.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Epirubicin plus CMF versus classical CMF Adjuvant Therapy

Primary outcome measure
1. 5 year disease-free survival
2. 5 year overall survival

Secondary outcome measures
1. Acute toxicity comparison between the two study arms
2. Quality of life and limited health economic comparisons between the two study arms, in a subset of 300 patients from designated centres

Overall study start date
30/04/1996

Completion date
31/07/2001

Eligibility

Key inclusion criteria
1. Histological diagnosis of invasive breast cancer
2. Clinically early stage disease
3. Definitive surgery (either wide local excision or mastectomy) to the breast with complete excision of tumour
4. In the opinion of the clinician there is a definite indication for adjuvant chemotherapy, or the patient has been randomised to receive chemotherapy in the ABC study
5. Fit to receive chemotherapy in either of the two arms
6. No previous radiotherapy or chemotherapy
7. Adequate renal, hepatic and bone marrow function
8. Randomisation within 6 weeks of surgery, ideally within 1 month
9. No previous malignancy except, basal cell carcinoma or in situ carcinoma of the cervix

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Target: 2000 patients. Recruited: 2028

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/04/1996

Date of final enrolment
31/07/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
CR UK Clinical Trials Unit, Institute for Cancer Studies, The University of Birmingham, Edgbaston
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
RES, University of Birmingham, Edgbaston
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Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Industry

Funder Name
Cancer Research UK

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
Pharmacia and Upjohn

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	02/11/2006		Yes	No
Results article	results	21/10/2008	25/01/2019	Yes	No