

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
Registration date 01/07/2001	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/01/2019	Condition category Cancer	☐ Individual participant data

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

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00003577

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

1. 5 year disease-free survival
2. 5 year overall survival

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

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)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Industry

Funder Name

Cancer Research UK

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

Pharmacia and Upjohn

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