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A randomised trial of standard anthracycline-based chemotherapy with fluorouracil, epirubicin and cyclophosphamide (FEC) or epirubicin and CMF (Epi-CMF) versus FEC followed by sequential docetaxel as adjuvant treatment for women with early breast cancer

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 17/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00033683

Protocol serial number
N/A

Study information

Scientific Title
A randomised trial of standard anthracycline-based chemotherapy with fluorouracil, epirubicin and cyclophosphamide (FEC) or epirubicin and CMF (Epi-CMF) versus FEC followed by sequential docetaxel as adjuvant treatment for women with early breast cancer

Acronym
TACT

Study objectives
Not provided at time of registration

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

Study type(s)
Treatment

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

Interventions
Control Arm A: 5- Fluorouracil (5-FU) (600 mg/m^2 intravenous [iv] bolus), Epirubicin (60 mg/m^2 iv bolus), Cyclophosphamide (600 mg/m^2 iv bolus) x eight cycles at three weekly intervals.

Control Arm B: Epirubicin (100 mg/m^2 iv bolus) x four cycles at three weekly intervals followed by Cyclophosphamide 100 mg/m^2 orally days one to 14 OR 600 mg/m^2 iv bolus days one, eight, Methotrexate 40 mg/m^2 iv bolus days one, eight, 5-FU 600 mg/m^2 iv bolus days one, eight x four cycles at four weekly intervals.

Study Arm: Docetaxel (100 mg/m^2) as one hour infusion for four cycles at three weekly intervals.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Anthracycline-based chemotherapy with fluorouracil, epirubicin and cyclophosphamide (FEC) or epirubicin and cyclophosphamide, methotrexate and 5-fluorouracil (CMF)

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/07/2003

Eligibility

Key inclusion criteria
1. Patients with operable histologically confirmed completely resected invasive breast cancer for whom adjuvant chemotherapy is indicated
2. No clinical or radiological evidence of locoregional or metastatic disease based on standard staging procedures at local centres
3. World Health Organisation (WHO) performance status of zero or one
4. Chemotherapy to start within eight weeks from date of definitive surgery
5. Aged over 18 years (no upper age limit)
6. Hormone receptor status to be determined prior to randomisation
7. Adequate renal, hepatic and bone marrow function
8. Signed written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
20/05/2001

Date of final enrolment
01/07/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)
Sutton, Surrey
United Kingdom
SM2 5NG

Sponsor information

Organisation
Sponsor not defined - Record supplied by Institute of Cancer Research

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (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

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	16/05/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes