

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/2415.shtml

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00033683

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Control Arm A: 5-Fluorouracil (5-FU) (600 mg/m² intravenous [iv] bolus), Epirubicin (60 mg/m² iv bolus), Cyclophosphamide (600 mg/m² iv bolus) x eight cycles at three weekly intervals.

Control Arm B: Epirubicin (100 mg/m² iv bolus) x four cycles at three weekly intervals followed by Cyclophosphamide 100 mg/m² orally days one to 14 OR 600 mg/m² iv bolus days one, eight, Methotrexate 40 mg/m² iv bolus days one, eight, 5-FU 600 mg/m² iv bolus days one, eight x four cycles at four weekly intervals.

Study Arm: Docetaxel (100 mg/m²) 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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

20/05/2001

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

3340

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**

England

United Kingdom

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

Sponsor details

c/o Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)

Section of Epidemiology

Brookes Lawley Building
Cotswold Road
Sutton, Surrey
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SM2 5NG

Sponsor type

Research organisation

Website

<http://www.ctu.mrc.ac.uk/ukcccr/home.html>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (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

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	16/05/2009		Yes	No