

# Trial of accelerated adjuvant chemotherapy with capecitabine in early breast cancer

<b>Submission date</b> 19/07/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/11/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-chemotherapy-after-surgery-for-breast-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

Prof David Cameron

### Contact details

Edinburgh Research Centre  
Western General Hospital  
Crewe Road South  
Edinburgh  
United Kingdom  
EH4 2XR

## Additional identifiers

### Clinical Trials Information System (CTIS)

2004-000066-13

### ClinicalTrials.gov (NCT)

NCT00301925

### Protocol serial number

N/A

# Study information

## Scientific Title

Trial of accelerated adjuvant chemotherapy with capecitabine in early breast cancer

## Acronym

TACT2

## Study objectives

A randomised, phase III clinical trial with a 2 x 2 factorial design addressing two hypotheses:

1. That accelerating Epirubicin will improve the efficacy of the sequential schedules (based originally on the NEAT epirubicin/CMF schedule).
2. That the substitution of CMF by Capecitabine will not be detrimental to patient outcome but will offer advantages in Quality of Life and/or toxicity.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Protocol TACT2: Version 1d approved on the 23/09/2005, UK Ethics Committee MREC ref: 04/MRE00/88

Version 3 approved on the 13/05/2008. Current protocol, version 5 approved July 2009

## Study design

Randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Early breast cancer

## Interventions

Epirubicin followed by cyclophosphamide, methotrexate and 5-fluorouracil (5-FU) (E-CMF)

Accelerated E-CMF

Epi-capecitabine

Accelerated epi-capecitabine

## Intervention Type

Drug

## Phase

Phase III

## Drug/device/biological/vaccine name(s)

Capecitabine, cyclophosphamide, epirubicin hydrochloride, fluorouracil, methotrexate, pegfilgrastim

## Primary outcome(s)

Disease-free survival (DFS)

## Key secondary outcome(s)

Overall survival (OS), distant disease-free survival (DDFS), tolerability (including Serious Adverse Events [SAE]), dose-intensity and toxicity, Detailed Toxicity and Quality of Life in the subset of patients studied.

## Completion date

01/09/2024

# Eligibility

## Key inclusion criteria

Patients with early breast cancer for whom treatment with anthracycline chemotherapy is indicated.

1. Histological diagnosis of invasive breast carcinoma
2. Completely resected disease with negative surgical margins (apart from deep margin if full thickness resection).
3. Early stage disease (T0-3 N0-2 M0) with no evidence of distant metastases on routine staging
4. Definite indication for adjuvant chemotherapy
5. ECOG status 0 or 1
6. Aged over 18 years (no upper age limit)
7. Fit to receive any of the trial chemotherapy regimens, with adequate bone marrow, hepatic, and renal function ie:
  - 7.1 Hb > 9g/dL; WBC > 3 × 10<sup>9</sup>/L; platelets > 100 × 10<sup>9</sup>/L
  - 7.2 Bilirubin within normal range (unless known Gilberts disease)
  - 7.3 AST/ALT = 1.5 × Upper limit of normal (ULN)
  - 7.4 Albumen within normal range
  - 7.5 Creatinine = 1.5 × ULN and calculated creatinine clearance using Cockcroft-Gault formula > 50 ml/min
  - 7.6 No active, uncontrolled infection
8. Signed TACT2 trial consent form
9. Randomisation within 8 weeks of surgery, but ideally within 1 month
10. No previous chemotherapy, hormonal therapy or radiotherapy for the treatment of pre-invasive or invasive cancer except:
  - 10.1 Previous radiotherapy for basal cell carcinoma
  - 10.2 Previous pre-operative endocrine therapy provided that there was no evidence of progression during this therapy, that it was for less than 6 weeks in duration, and was stopped at least one month prior to trial entry
11. No previous malignancy except in the case of DCIS, or basal cell carcinoma or cervical carcinoma in situ, or where the patient has been disease-free for 10 years, and where treatment consisted solely of resection.
12. Non-pregnant and non-lactating, with no intention of pregnancy during chemotherapy, and prepared to adopt adequate contraceptive measures if pre-menopausal and sexually active
13. No concomitant medical, psychiatric or geographic problems that might prevent completion of treatment or follow-up

## Participant type(s)

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

4391

**Key exclusion criteria**

1. Only cytological proof of malignancy
2. No evidence of invasive breast cancer
3. Previous invasive breast cancer or bilateral breast cancer (surgically treated DCIS or LCIS is allowed)
4. Locally advanced breast cancer (T4 and/or N3 disease)
5. Patients who have had breast conserving surgery in whom there is a contra-indication for, or refusal of post-operative radiotherapy
6. Patients with positive surgical margins unless either:
  - 6.1 Deep surgical margin involvement following full thickness resection
  - 6.2 Non-invasive cancer at surgical margins and a decision to perform mastectomy on completion of chemotherapy has already been made
7. Patients not able or willing to give informed consent
8. Patients known not to be available for a minimum of 5 years' follow-up
9. Patients with known serious viral infection such as active Hepatitis B, Hepatitis C or HIV
10. Patients with significant cardiac disease, such as impaired left ventricular function or active angina (requiring regular anti-anginal medication and/or resulting in restricted physical activity)
11. Patients with a history of significant renal impairment or disease
12. Simultaneous participation in the active intervention phase of another treatment trial
13. Being approached and recruited into the active intervention phase of another treatment trial two months before or after recruitment into TACT2

**Date of first enrolment**

01/12/2005

**Date of final enrolment**

05/12/2008

**Locations**

**Countries of recruitment**

United Kingdom

Scotland

**Study participating centre**  
**Western General Hospital**  
Edinburgh  
United Kingdom  
EH4 2XR

## Sponsor information

### Organisation

The Institute of Cancer Research (UK)

### ROR

<https://ror.org/043jzw605>

## Funder(s)

### Funder type

Industry

### Funder Name

Cancer Research UK (CRUK) (UK) (ref: C1491/A4858)

### 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

Hoffman La-Roche (UK)

### Alternative Name(s)

Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

Switzerland

### Funder Name

Amgen Ltd (UK)

### Funder Name

Pfizer UK

### Alternative Name(s)

Pfizer Ltd, Pfizer Limited

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2017		Yes	No
<a href="#">Results article</a>		02/11/2023	06/11/2023	Yes	No
<a href="#">Plain English results</a>			26/10/2022	No	Yes