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Trial of accelerated adjuvant chemotherapy with capecitabine in early breast cancer

Submission date 19/07/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/09/2004	**Overall study status** Completed	
Last Edited 06/11/2023	**Condition category** Cancer	

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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00301925

Clinical Trials Information System (CTIS)
2004-000066-13

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 ´ 109/L; platelets > 100 x 109/L
7.2 Bilirubin within normal range (unless known Gilberts disease)
7.3 AST/ALT = 1.5 x Upper limit of normal (ULN)
7.4 Albumen within normal range
7.5 Creatinine = 1.5 x ULN and calculated creatinine clearance using Cockroft-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?
Results article	results	01/07/2017		Yes	No
Results article		02/11/2023	06/11/2023	Yes	No
Plain English results			26/10/2022	No	Yes