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A randomised phase III trial of gemcitabine in paclitaxel-containing, epirubicin-based, adjuvant chemotherapy for women with early stage breast cancer

Submission date
01/07/2001

Recruitment status
No longer recruiting

Registration date
01/07/2001

Overall study status
Completed

Last Edited
17/10/2018

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-002927-41

IRAS number

ClinicalTrials.gov number
NCT00039546

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised phase III trial of gemcitabine in paclitaxel-containing, epirubicin-based, adjuvant chemotherapy for women with early stage breast cancer

Acronym
TANGO

Study objectives
In women with early stage breast cancer, the addition of gemcitabine to paclitaxel-containing, epirubicin-based, adjuvant chemotherapy provides significantly superior disease-free and overall survival, without excess toxicity or prolonged adverse impact on quality of life.

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)
Hospital

Study type(s)
Treatment

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

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

Interventions

Control arm: Epirubicin 90 mg/m^2 (day one) + Cyclophosphamide 600 mg/m^2 (day one); four cycles, three weekly intervals followed by Paclitaxel 175 mg/m^2 (day one); four cycles at three weekly intervals.

Research arm: Epirubicin 90 mg/m^2 (day one) + Cyclophosphamide 600 mg/m^2 (day one); four cycles at three weekly intervals followed by Gemcitabine 1250 mg/m^2 (days one and eight) + Paclitaxel 175 mg/m^2 (day one); four cycles at three weekly intervals.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Epirubicin, cyclophosphamide, paclitaxel, gemcitabine

Primary outcome measure
Five-year disease-free survival

Secondary outcome measures
Ten-year overall survival, toxicity, dose intensity, tolerability and serious adverse events

Overall study start date
22/08/2001

Completion date
26/11/2004

Eligibility

Key inclusion criteria
1. Histological diagnosis of invasive breast carcinoma
2. Completely resected early stage disease
3. Definite indication for adjuvant chemotherapy
4. Any nodal status
5. Any hormone receptor status
6. Fit to receive either of the trial chemotherapy regimens. Adequate bone marrow, hepatic, and renal function.
7. Eastern Cooperative Oncology Group (ECOG) performance status of zero to two
8. Written informed consent
9. No previous chemotherapy or radiotherapy
10. Radiotherapy intent is known (this must be stated at the point of randomisation)
11. Randomisation within eight weeks of surgery, but ideally within one month
12. No previous malignancy except basal cell carcinoma or cervical carcinoma in situ, unless disease-free for ten years, after surgical treatment only
13. 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
14. No concomitant medical or psychiatric problems that might prevent completion of treatment or follow-up

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3152

Key exclusion criteria
Any of the above criteria not satisfied

Date of first enrolment
22/08/2001

Date of final enrolment
26/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
CRUK Clinical Trials Unit
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
The University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Industry

Funder Name
Bristol Myers-Squibb

Alternative Name(s)
Bristol-Myers Squibb Company, BMS

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Pharmacia and Upjohn

Funder Name
Eli Lilly and Company

Alternative Name(s)
Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location

United States of America

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	safety substudy results	19/08/2008		Yes	No
Results article	results	01/06/2017		Yes	No