

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	<input checked="" 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

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-002927-41

ClinicalTrials.gov (NCT)

NCT00039546

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Control arm: Epirubicin 90 mg/m² (day one) + Cyclophosphamide 600 mg/m² (day one); four cycles, three weekly intervals followed by Paclitaxel 175 mg/m² (day one); four cycles at three weekly intervals.

Research arm: Epirubicin 90 mg/m² (day one) + Cyclophosphamide 600 mg/m² (day one); four cycles at three weekly intervals followed by Gemcitabine 1250 mg/m² (days one and eight) + Paclitaxel 175 mg/m² (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(s)

Five-year disease-free survival

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

CRUK Clinical Trials Unit

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

The University of Birmingham (UK)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Industry

Funder Name

Bristol Myers-Squibb

Alternative Name(s)

Bristol-Myers Squibb Company, Bristol Myers Squibb, Bristol-Myers 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, Eli Lilly & Co

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

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