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

Submission date	Recruitment status	[X] Prospectively registered		
01/07/2001	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
01/07/2001	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
17/10/2018	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Shrushma Loi

Contact details

CRUK Clinical Trials Unit Institute for Cancer Studies The University of Birmingham Edgbaston Birmingham United Kingdom B15 2TT +44 (0)121 414 3789 tango@trials.bham.ac.uk

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

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