

The SBG 2004-1/ABCSG 25/GBG53 study (the Panther study)

Submission date 19/06/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 02/04/2020	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

Contact name
Prof Jonas Bergh

Contact details
Department of Oncology
Karolinska University Hospital
Stockholm
Sweden
SE-171 76

Additional identifiers

Clinical Trials Information System (CTIS)
2007-002061-12

ClinicalTrials.gov (NCT)
NCT00798070

Protocol serial number
SBG 2004-1/ABCSG 25/GBG53

Study information

Scientific Title

A randomised phase III study comparing biweekly and tailored epirubicin plus cyclophosphamide followed by biweekly tailored docetaxel (A-arm) versus three weekly epirubicin plus cyclophosphamide, 5-fluorouracil followed by docetaxel (B-arm) in lymph node positive breast cancer patients - a continuation of the feasibility part of the SBG 2004-1 study

Acronym

The Panther Study

Study objectives

The aim of the study is to compare breast cancer recurrence-free survival (BCRFS; local, regional, distant breast cancer relapse or death due to breast cancer) in the tailored therapy arm compared with the fixed dose arm.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Board in Stockholm (Regionala etikprövningsnämnden i Stockholm), 15/01/2007, ref: 04-647/1

Study design

Phase III open prospective randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lymph node positive breast cancer patients

Interventions

Tailored therapy arm:

Tailored epirubicin (38 - 120 mg/m²) and cyclophosphamide (450 - 1200 mg/m²) will be given intravenously for four courses with granulocyte colony stimulating factor (G-CSF) support. Courses should be given with a biweekly interval followed by four courses docetaxel 75 - 100 mg/m² with G-CSF support. The first course will start at EC Step 1, epirubicin 90 mg/m² and cyclophosphamide 600 mg/m². This is followed by four courses docetaxel 75 - 100 mg/m² biweekly with G-CSF support. Starting dose of docetaxel Step 0 is 75 mg/m².

Fixed dose arm:

Three courses of 5-fluorouracil (500 mg/m²), epirubicin (100 mg/m²) and cyclophosphamide 500 mg/m², given with a 3-week interval, will be followed by three courses of docetaxel 100 mg/m² given with a 3-week interval.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Epirubicin, cyclophosphamide, docetaxel, 5-fluorouracil

Primary outcome(s)

Breast cancer relapse-free survival (local, regional or systemic relapse or death due to breast cancer), assessed during follow-up at 4, 8, 12, 16, 20 months and 2 years and then every 6 months until 5 years. From this point, assessment will be carried out annually until 10 years.

Key secondary outcome(s)

The following three outcomes will be assessed during follow-up at 4, 8, 12, 16, 20 months and 2 years and then every 6 months until 5 years. From this point, assessment will be carried out annually until 10 years:

1. Distant disease-free survival (DDFS)
2. Event-free survival
3. Overall survival
4. Health-related quality of life, assessed at baseline, 6 and 15 weeks during treatment and then at 4, 8 and 12 months during follow up
5. Outcome in relation to tumour biological factors and polymorphism patterns

Completion date

01/08/2011

Eligibility

Key inclusion criteria

Current inclusion criteria as of 24/01/2011:

1. Histologically proven invasive primary breast cancer, with at least 5 (recommended 10) removed axillary lymph nodes. Interval between definitive surgery that includes axillary lymph node dissection and registration must be less than 60 days. Paraffin block from the primary tumour must be retained (not mandatory for Austrian sites). Frozen tumour tissue is strongly recommended to be stored.
2. Receptor-negative or -positive tumours with 1 or more positive axillary lymph nodes (more than 0.2 mm) OR axillary node negative breast cancers if the primary tumour is larger than 20 mm and receptor negative (Er and Pgr with no receptor content) and being Elston grade III. In Germany high-risk node-negative breast cancer patients are not eligible until labelling for docetaxel includes node-negative disease.
3. Macroscopically and microscopically radical surgery, free margins (no cancer cells at borders of resection)
4. No proven distant metastases: negative pulmonary X-ray, bone scintigram (when clinical signs of skeletal metastases or elevated alkaline phosphatase [ALP] is observed) supplemented with normal conventional X-ray of hot spots, normal liver function test and haematological function tests. Abnormal values: computed tomography (CT) or ultrasound of the liver (patient can be included if no metastases are demonstrated).
5. Female aged 18 - 65 years
6. Ambulant patients (Eastern Cooperative Oncology Group [ECOG] 1 or less)
7. No major cardiovascular morbidity: New York Heart Association (NYHA) grade I or II
8. Written informed consent according to the local ethics committee requirements

9. Patients of childbearing potential should have a negative pregnancy test within seven days of registration (in Austria, pregnancy tests have to be repeated monthly during the treatment phase)

Previous inclusion criteria:

1. Histologically proven invasive primary breast cancer, with at least 5 (recommended 10) removed axillary lymph nodes. Interval between definitive surgery that includes axillary lymph node dissection and registration must be less than 60 days. Paraffin block from the primary tumour must be retained (not mandatory for Austrian sites). Frozen tumour tissue is strongly recommended to be stored.
2. Receptor-negative or -positive tumours with 1 or more positive axillary lymph nodes (greater than 0.2 mm)
3. Macroscopically and microscopically radical surgery, free margins (no cancer cells at borders of resection)
4. No proven distant metastases: negative pulmonary X-ray, bone scintigram (when clinical signs of skeletal metastases or elevated alkaline phosphatase [ALP] is observed) supplemented with normal conventional X-ray of hot spots, normal liver function test and haematological function tests. Abnormal values: computed tomography (CT) or ultrasound of the liver (patient can be included if no metastases are demonstrated).
5. Female age 18 - 65 years
6. Ambulant patients (Eastern Cooperative Oncology Group [ECOG] 1 or less)
7. No major cardiovascular morbidity: New York Heart Association (NYHA) grade I or II
8. Written informed consent according to the local ethics committee requirements
9. Patients of childbearing potential should have a negative pregnancy test within seven days of registration (in Austria, pregnancy tests have to be repeated monthly during the treatment phase)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

Current exclusion criteria as of 24/01/2011:

1. Previous neo-adjuvant treatment
2. Non-radical surgery (histopathological positive margins)
3. A primary breast cancer patient being 35 years or younger considered suitable for adjuvant chemotherapy (may be receptor negative or positive, HER-2/neu negative or positive, with or without axillary lymph node metastases)
4. Proven distant metastases
5. Pregnancy or lactation

6. Other serious medical condition
7. Previous or concurrent malignancies at other sites, except basal cell carcinoma and/or squamous cell carcinoma in situ of the skin or cervix. Patients with previous breast cancer (invasive and/or ductal carcinoma in situ) in the other breast without loco-regional (large lung volumes) radiotherapy, without objective findings for relapse, with greater than 5 years since diagnosis can be included.
8. Abnormal laboratory values precluding the possibility to safely deliver the cytotoxic agents used in the study
9. Hypersensitivity to drugs formulated in polysorbate 80
10. Peripheral neuropathy grade greater than or equal to 2

Previous exclusion criteria:

1. Previous neo-adjuvant treatment
2. Non-radical surgery (histopathological positive margins)
3. Proven distant metastases
4. Pregnancy or lactation
5. Other serious medical condition
6. Previous or concurrent malignancies at other sites, except basal cell carcinoma and/or squamous cell carcinoma in situ of the skin or cervix. Patients with previous breast cancer (invasive and/or ductal carcinoma in situ) in the other breast without loco-regional (large lung volumes) radiotherapy, without objective findings for relapse, with greater than 5 years since diagnosis can be included.
7. Abnormal laboratory values precluding the possibility to safely deliver the cytotoxic agents used in the study
8. Hypersensitivity to drugs formulated in polysorbate 80
9. Peripheral neuropathy grade greater than or equal to 2

Date of first enrolment

01/02/2007

Date of final enrolment

01/08/2011

Locations

Countries of recruitment

Austria

Germany

Sweden

Study participating centre

Karolinska University Hospital

Stockholm

Sweden

SE-171 76

Sponsor information

Organisation

Karolinska University Hospital

ROR

<https://ror.org/00m8d6786>

Organisation

Paracelsus University

Organisation

Städt. Kliniken Frankfurt-Höchst

Funder(s)

Funder type

Industry

Funder Name

Swedish Cancer Society (Sweden)

Alternative Name(s)

Swedish Cancer Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Funder Name

ALF Foundation, Stockholm County Council (Sweden)

Funder Name

Sanofi-Aventis (Sweden)

Funder Name

Sanofi-Aventis (Austria)

Funder Name

Sanofi-Aventis (Germany)

Funder Name

Sanofi-Aventis (Europe)

Funder Name

Amgen (Sweden)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Amgen (Germany)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Amgen (Europe)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/11/2016		Yes	No
Results article	results	01/05/2020	02/04/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes