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

Submission date 19/06/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/08/2007	**Overall study status** Completed	
Last Edited 02/04/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.kpeks.se/sbg20041

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

EudraCT/CTIS number
2007-002061-12

IRAS number

ClinicalTrials.gov number
NCT00798070

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Lymph node positive breast cancer patients

Interventions
Tailored therapy arm:
Tailored epirubicin (38 - 120 mg/m^2) and cyclophosphamide (450 - 1200 mg/m^2) 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 /m^2 with G-CSF support. The first course will start at EC Step 1, epirubicin 90 mg/m^2 and cyclophosphamide 600 mg/m^2. This is followed by four courses docetaxel 75 - 100 mg/m^2 biweekly with G-CSF support. Starting dose of docetaxel Step 0 is 75 mg/m^2.

Fixed dose arm:
Three courses of 5-fluorouracil (500 mg/m^2), epirubicin (100 mg/m^2) and cyclophosphamide 500 mg/m^2, given with a 3-week interval, will be followed by three courses of docetaxel 100 mg /m^2 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 measure
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.

Secondary outcome measures
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

Overall study start date
01/02/2007

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)
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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).
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Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Female

Target number of participants
2000

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

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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

Sponsor details
c/o Prof Jonas Bergh
Radiumhemmet
Department of Oncology
Karolinska University Hospital
Stockholm
Sweden
SE-171 76
+46 (0)8 51770000
jonas.bergh@ki.se

Sponsor type
University/education

Website
http://www.karolinska.se/en

ROR
https://ror.org/00m8d6786

Organisation
Paracelsus University

Sponsor details

c/o Richard Greil, MD, Professor
Austrian Breast & Colorectal Cancer Study Group (ABCSG)
Department of Internal Medicine III
Salzburg
Austria
A-5020

Sponsor type
University/education

Organisation
Städt. Kliniken Frankfurt-Höchst

Sponsor details
c/o Volker Möbus, MD, Professor
German Breast Group (GBG)
Frauenklinik
Gotenstrasse 6-8
Frankfurt/Höchst
Germany
D-65929

Sponsor type
Hospital/treatment centre

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

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?
Results article	results	08/11/2016		Yes	No
Results article	results	01/05/2020	02/04/2020	Yes	No