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Capecitabine with/without vinorelbine after sequential dose-dense epirubicin and paclitaxel in high-risk early breast cancer

Submission date 24/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/09/2009	**Overall study status** Completed	
Last Edited 01/09/2009	**Condition category** Cancer	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RC 40

Study information

Scientific Title
Phase I/II single-arm interventional pilot study of capecitabine with or without vinorelbine after sequential dose-dense epirubicin and paclitaxel in high-risk early breast cancer

Study objectives
Integration of the non-cross-resistant chemotherapeutic agents capecitabine and vinorelbine into a intensified dose-dense sequential anthracycline and taxane containing regimen in high-risk early breast cancer (EBC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee State of Hessen, Germany approved on the 15th February 2003 (ref: 38/2003)

Study design
Single-arm, interventional phase I/II pilot study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Patients with stage II/IIIA EBC (four or more positive lymph nodes) received post-operative intensified dose-dense sequential epirubicin and paclitaxel with filgrastim and darbepoetin alfa, followed by capecitabine alone (dose levels 1 and 3) or with vinorelbine (dose levels 2 and 4). Capecitabine was given on days 1 to 14 every 21 days at 1,000 or 1,250 mg/m2 twice daily (dose levels 1/2 and 3/4, respectively). Vinorelbine 25 mg/m2 was given on days 1 and 8 of each 21-day course (dose levels 2 and 4). Treatment duration was 24 weeks. Median duration of follow-up is 35.2 months.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Capecitabine, vinorelbine, epirubicin, paclitaxel, filgrastim, darbepoetin alfa

Primary outcome measure
Toxicity, assessed during treatment

Secondary outcome measures
1. Disease free survivial at 3 years
2. Overall survival at 3 years

Overall study start date
15/10/2003

Completion date
15/07/2006

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years, female
2. Histologically confirmed stage II/IIIA breast cancer with four or more positive axillary lymph nodes
3. Had undergone surgery (complete surgical resection [R0] of breast tumour and axilla) before inclusion in the study
4. Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
5. Left ventricular ejection fraction within the normal institutional range
6. Adequate haematological, renal and hepatic function
7. Provided written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
Approximately 50 patients

Key exclusion criteria
1. Inflammatory breast cancer
2. Received neoadjuvant endocrine therapy, chemotherapy or radiotherapy
3. Known dihydropyrimidine dehydrogenase deficiency
4. Creatinine clearance less than 30 mL/min
5. Impaired organ function
6. Metastatic disease

Date of first enrolment
15/10/2003

Date of final enrolment
15/07/2006

Locations

Countries of recruitment
Germany

Study participating centre
Staedtisches Klinikum Frankfurt-Hoechst
Frankfurt / M
Germany
65929

Sponsor information

Organisation
AGO Breast Study Group (Arbeitsgeinschaft für Gynäkolgische Onkologie) (Germany)

Sponsor details
c/o Prof Dr. V. Möbus
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Sponsor type
Research organisation

ROR
https://ror.org/01kjfnp05

Funder(s)

Funder type
Industry

Funder Name
Roche Pharma (Germany)

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

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