

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

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>24/08/2009   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>01/09/2009 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>01/09/2009       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Volker Moebus

### Contact details

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## Additional identifiers

### Protocol serial number

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)

**Primary study design**

Interventional

**Study design**

Single-arm, interventional phase I/II pilot study

**Study type(s)**

Treatment

**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/m<sup>2</sup> twice daily (dose levels 1/2 and 3/4, respectively). Vinorelbine 25 mg/m<sup>2</sup> 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(s)**

Toxicity, assessed during treatment

**Key secondary outcome(s)**

1. Disease free survival at 3 years
2. Overall survival at 3 years

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

65 Years

## Sex

Female

## 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 (Arbeitsgemeinschaft für Gynäkologische Onkologie) (Germany)

**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

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration