FBCG

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Title: Comparison of vinorelbine *versus* docetaxel, and trastuzumab *versus* no trastuzumab as adjuvant treatments of early breast cancer.
FinHer study

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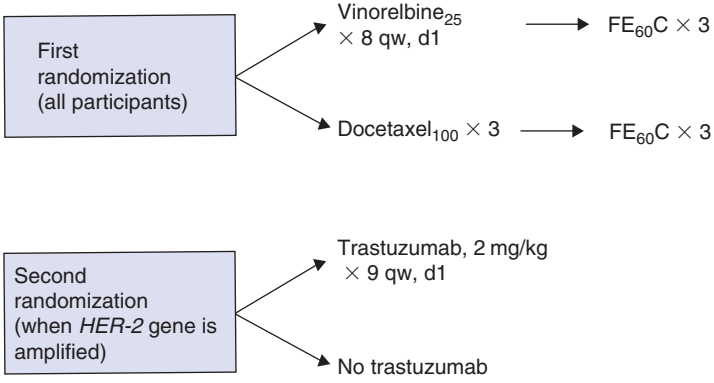
Summary:

- Opened in November 2000
- Target accrual: 1010 patients

Objectives:

- To compare tolerability, safety and efficacy of single-agent vinorelbine and single-agent docetaxel as adjuvant treatments of early breast cancer with moderate to high risk for cancer recurrence.
- To assess tolerability, safety and efficacy of trastuzumab given concomitantly with vinorelbine or docetaxel as adjuvant treatment of early breast cancer with moderate to high risk for cancer recurrence.

Scheme:



Update:

- Study closed in September 2003 with 1010 patients (1009 eligible).
- Three-year results have been published (Joensuu H *et al.*, *New Engl J Med* 2006; 354: 809–820).

Related Publications: Joensuu H *et al.*, *New Engl J Med* 2006; 354: 809–820.

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Topics:
- HER2 positive patients
- Taxanes
- Trastuzumab
- Vinorelbine
- Cardiac function
- Anthracyclines
- Innovative schedules

Keywords: Adjuvant treatment, HER-2 positive breast cancer, trastuzumab

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Title: Randomized phase III study comparing single-agent docetaxel followed by 5-FU, epirubicin and cyclophosphamide (FEC) to docetaxel plus Xeloda followed by cyclophosphamide, epirubicin and Xeloda (CEX) as adjuvant treatment for early breast cancer.
FinXX Study

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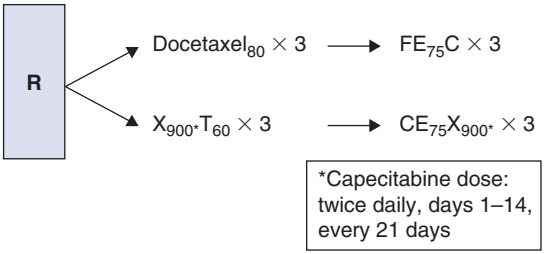
Summary:

- Opened in January 2004
- Target accrual: 1500 patients

Objectives:

- Primary endpoint: relapse-free survival (RFS) at 5 years.
- Secondary endpoint: safety and overall survival.

Scheme:



Update:

- Study ongoing, 977 patients accrued by the end of February 2006.

Related Publications: None available

Topics:

- Capecitabine
- Taxanes

Keywords: Adjuvant treatment, capecitabine, taxanes

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Title: A multicenter phase III open randomised trial of the efficacy of exercise in the prevention of long-term adverse effects of adjuvant treatments and breast cancer recurrences in women with primary breast cancer.
BREX 01-2004 Study

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Summary:

- Opened in December 2005.
- Target accrual: 600 patients (300 per arm).
- Patients are randomised into exercise intervention or control groups. The exercise intervention consists of both supervised and home training. The control group maintain previous physical activity and exercise habits.

Objectives:

- To investigate whether regular exercise after adjuvant treatments of breast cancer could:
  (1) prevent osteoporosis (primary outcome)
  (2) improve quality of life (primary outcome)
  (3) improve weight control, and muscular and cardiovascular fitness (secondary outcome)
  (4) reduce the risk of breast cancer recurrence (secondary outcome)
  (5) prevent other diseases and reduce all-cause mortality in patients with primary breast cancer (secondary outcome)

Scheme: None available

Update:

- Study ongoing

Related Publications: None available

Topics:

- Bone mineral density

Keywords: Intervention, prevention, primary breast cancer, osteoporosis

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