SBG

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Title: High-dose chemotherapy + autologous stem cell transplantation compared with dose escalating chemotherapy in breast cancer with poor prognosis ⩾8 positive lymph nodes or ⩾5 lymph nodes combined with R-combined with either G II–III or high S-phase. A randomized study. **SBG 9401**

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Summary:

- Closed in March 1998 (opened on 1 March 1994)
- Target accrual: 500 patients

Objectives:

- To compare disease-free survival of high-risk breast cancer patients treated with either high-dose chemotherapy + autologous stem cell transplantation or dose-escalated chemotherapy (CEC) both as adjuvant treatment.
- To compare survival, safety, dose-intensity and total dose between the two treatment arms.
- To assess quality of life.

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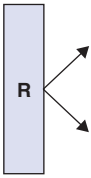
Scheme:



Arm A
Dose-escalating FEC + filgrastim → tamoxifen for 5 years + RT 9 cycles

Arm B
FEC 3 cycles + filgrastim (cycle 3) → high-dose chemotherapy + PBPC support → tamoxifen for 5 years + RT

Arm A:

Dose escalating FEC

I step:	5 FU 600 mg/m^2, Epirubicin 75 mg/m^2, cyclo 900 mg/m^2
II step:	5 FU 600 mg/m^2, Epirubicin 90 mg/m^2, cyclo 1200 mg/m^2
III step:	5 FU 600 mg/m^2, Epirubicin 105 mg/m^2, cyclo 1500 mg/m^2
IV step:	5 FU 600 mg/m^2, Epirubicin 120 mg/m^2, cyclo 1800 mg/m^2

(Two minus steps too)

Arm B:

Induction FEC

Cycles 1–2:	5 FU 600 mg/m^2, Epirubicin 60 mg/m^2, cyclo 600 mg/m^2
Cycle 3:	5 FU 600 mg/m^2, Epirubicin 60 mg/m^2, cyclo 1200 mg/m^2 + G-CSF

High-dose CT:

Cycle 4:	(cyclophosphamide 1.5 g/m^2 + thiotepa 125 mg/m^2 + carboplatin 200 mg/m^2) days −7 to −4

Update:

- Study closed in March 1998.
- 525 patients randomized.
- Reported in *The Lancet* 2000.
- New update 2003.
- Final update 2008.

Related Publications:

Brandberg Y, Michelson H, Nilsson B *et al.* Quality of life in women with breast cancer during the first year after random assignment to adjuvant treatment with marrow supported high-dose chemotherapy with cyclophosphamide, thiothepa, and carboplatin or tailored therapy with fluorouracil, epirubicin, and cyclophosphamide: Scandinavian Breast Group Study 9401. *J Clin Oncol* 2003; 21: 6359–3664.

Topics:

- High dose chemotherapy
- Treatment tailoring

Keywords: Anthracyclines, high-dose therapy, node positive breast cancer

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Title: Standard CEF-60 *versus* tailored CEF in high-risk primary breast cancer.
SBG CEF-60, SBG 2000-1

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Summary:

- The study was open from February 2001 to August 2003. 1535 patients received the first course of standard FEC, accrual completed.
- 1052 patients were randomized.

Objectives:

- To study whether retrospective observations indicating suboptimal effect of CT in patients not experiencing toxicity can be confirmed in a prospective study.
- To study whether dose-escalation in patients not experiencing leukopenia improves prognosis.

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Scheme: First cycle of CEF-60:

- If WBG GR III/IV: continue with 6 cycles of CEF-60/reduced dose
- If WBG GR 0–II: randomize to 6 cycles of CEF-60/escalated CEF

Update:

- First analysis based on event rate 2007/2008.

Related Publications: None available

Topics:

- Treatment tailoring

Keywords: Anthracycline, treatment tailoring, node negative breast cancer, node positive breast cancer

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Title: HABITS – Hormonal replacement therapy after breast cancer diagnosis – is it safe?
BIG 03-97

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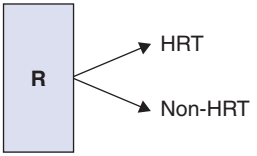
Summary:

- Opened in 1998, closed in December 2003 for safety reasons
- Target accrual: 1300 patients

Objectives:

- To investigate in women with radically treated in situ, stage I or early stage II breast cancer if the use of hormone replacement therapy (HRT for menopausal symptoms) is safe concerning risk of breast cancer recurrence.
- To look at quality of life and risk of breast cancer death.

Scheme:



Update:

- At the end of accrual 434 women were randomized. After a medium follow-up of 2.1 years, 26 women in the HRT group and seven in the non-HRT group had a new breast cancer event, corresponding to a relative hazard for HRT treatment of 3.5 (95% confidence interval 1.5–8.1). During 2005 and 2006 a new monitoring round was completed and new analyses presented during autumn 2006.

Related Publications: Holmberg L, Anderson H, for the HABITS-steering and data monitoring committees. HABITS, a randomised comparison: trial stopped. *Lancet* 2004; 363: 453–455.

Topics: None available

Keywords: Breast cancer, menopausal symptoms, hormonal replacement therapy

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Title: A phase II study continuing into a randomized phase III study comparison of safety, feasibility and efficacy of: dose dense and tailored and dose escalated epirubicin + cyclophosphamide followed by docetaxel (dEC→T) or dose dense epirubicin + cyclophosphamide followed by docetaxel (EC→T) or docetaxel + doxorubicin + cyclophosphamide (TAC) in lymph node positive breast cancer patients.
SBG 2004-1 STUDY

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Summary:

- First patient randomized in December 2004
- Randomized feasibility study: Target accrual: 120 patients
- Randomized phase III 2-armed study: 900 patients

Objectives:

- For the phase II part: evaluate safety and feasibility in the three treatment arms.
- Evaluate the dose intensity in the three treatment arms.

For the Phase III Part:

Primary Objective:

- Compare breast cancer recurrence-free survival (BCRFS), in the dtEC→dtT (tailored doses) arm compared with the EC→T (fixed doses) arm.

Secondary Objectives:

- Compare distant disease free survival (DDFS).
- Compare event-free survival (breast cancer relapse, contralateral breast cancer, other malignancies).
- Compare overall survival (OS).

Additional aims/biological markers.

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Scheme:

Dose dense and tailored therapy, every second week	A dEC × 4 → dT × 4
Dose dense therapy with fixed doses every second week	B EC × 4 → T × 4
Fixed doses every third week	C TAC × 6

Update:

- 120 patients entered on 8 May 2005.

Related Publications: None available

Topics:

- Dose densification

Keywords: Adjuvant chemotherapy, dose dense, node positive breast cancer, anthracyclins, taxanes

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