GONO MIG

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Title: Standard CEF *versus* accelerated CEF as adjuvant chemotherapy in node-positive or high-risk node-negative (T > 2 cm, age <35 years, G3, negative hormone receptors or high TL1 or S-phase) breast cancer. A phase III randomized trial.
MIG-1

Coordinator(s): M. Venturini
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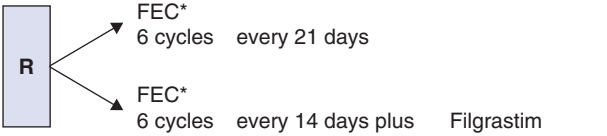
Summary:

- Closed in June 1997 (opened in November 1992)
- Target accrual: 1200 patients

Objective:

- To evaluate overall survival and disease-free survival in early breast cancer patients treated with standard CEF or accelerated CEF as adjuvant chemotherapy.

Scheme:



* Cyclo 600 mg/m^2 + Epi ADM 60 mg/m^2 + 5FU 600 mg/m^2

Update:

- Closed in June 1997.
- Patients randomized: 1214.

Related Publications: Dose-Dense Adjuvant Chemotherapy in Early Breast Cancer Patients: Results From a Randomized Trial. *J Nat Cancer Inst* 2005; 97: 1724–1733.

HER2 expression and efficacy of dose-dense anthracycline containing adjuvant chemotherapy in breast cancer patients. *Br J Cancer* 2005; 93: 7–14.

Topics:

- Dose densification

Keywords: Dose-dense, chemotherapy

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Title: Epirubicin plus paclitaxel *versus* cyclophosphamide, epirubicin and 5-fluorouracil as adjuvant chemotherapy in node-positive breast cancer patients. A phase III randomized study.
MIG-5

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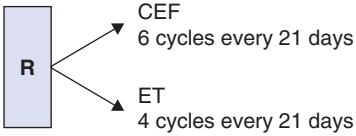
Summary:

- Opened in November 1996
- Target accrual: 1000 patients

Objective:

- To evaluate overall survival and disease-free survival in early breast cancer patients treated with epirubicin plus paclitaxel or CEF as adjuvant chemotherapy.

Scheme:



CEF = cyclo 600 mg/m^2 + Epi ADM 60 mg/m^2 + 5FU 600 mg/m^2
ET = ADM 90 mg/m^2 + paclitaxel 175 mg/m^2 (3-hour infusion)

Update:

- Closed in January 2001.
- 1055 patients recruited.

Related Publications: None available

Topics:

- Node-positive breast cancer

Keywords: Adjuvant chemotherapy

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Title: A phase III randomized study of sequential epidoxorubicin plus cyclophosphamide followed by docetaxel (EC D) *versus* a combination of 5-fluorouracil, epidoxorubicin and cyclophosphamide (FEC) as adjuvant treatment of node-negative early breast cancer patients.

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Summary:

- Active since 13 November 2003
- Target accrual: 3000 patients

Objective:

- To compare the disease-free survival (DFS) in patients treated with the sequential EC D regimen to that in patients treated with the FEC regimen.

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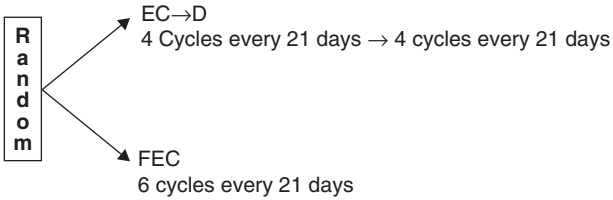
Scheme:



EC→D = epidoxorubicin 90 mg/m^2 + cyclophosphamide 600 mg/m^2 → docetaxel 100 mg/m^2

FEC = fluorouracil 600 mg/m^2 + epidoxorubicin 75 mg/m^2 + cyclophosphamide 600 mg/m^2

Update:

- Patients randomized: 812 as of 30 September 2006.
- Study ongoing.

Related Publications: None available

Topics:

- Node-negative breast cancer

Keywords: Adjuvant chemotherapy, taxanes

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Title: A phase III randomized study of EC followed by paclitaxel *versus* FEC followed by paclitaxel, all given either every 3 or 2 weeks supported by pegfilgrastim, for node-positive breast cancer patients.

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Summary:

- Active since 19 March 2003
- Target accrual: 2000 patients

Objective:

- To evaluate the efficacy in terms of disease-free survival (DFS) of 5-fluorouracil addition to EC → T regimen and to determine the efficacy of dose-dense chemotherapy.

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Scheme:

Arm A EC × 4 cycles → T × 4 cycles q 3 weeks.	Arm C EC × 4 cycles → T × 4 cycles q. 2 weeks. + pegfilgrastim
Arm B FEC × 4 cycles → T × 4 cycles q 3 weeks.	Arm D FEC × 4 cycles → T × cycles 4 q. 2 weeks. + pegfilgrastim

Chemotherapy

- EC – Epirubicin 90 mg/m^2 IV bolus, Cyclophosphamide 600 mg/m^2 IV bolus, every 2 or 3 weeks
- T – Paclitaxel 175 mg/m^2 IV 3-hour infusion, every 2 or 3 weeks
- FEC – Fluorouracil 600 mg/m^2 IV bolus, Epirubicin 90 mg/m^2 IV bolus, Cyclophosphamide 600 mg/m^2 IV bolus, every 2 or 3 weeks
- Pegfilgrastim 1 vial (6 mg) 24 hours after each cycle of chemotherapy will administered to patients in ARM C and ARM D

Update:

- Closed in July 2006.
- 2091 patients recruited.

Related Publications: None available

Topics:

- Node-positive breast cancer.

Keywords: Adjuvant chemotherapy, taxanes, dose-dense

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Title: Prevention of chemotherapy-induced menopause by temporary ovarian suppression with triptorelin *versus* control in young breast cancer patients. A randomized phase III multicenter study.

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Summary:
- Active since 29 May 2003.
- Target accrual: 280

Scheme:
- ARM A = Chemotherapy alone
- ARM B = Chemotherapy + Triptorelin

Update:
- Patients randomized: 177 as of 30 September 2006.
- Study ongoing.

Related Publications: None available

Topics:
- Fertility and chemotherapy

Keywords: Fertility, drug-induced amenorrhea, chemotherapy

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Title: Letrozole adjuvant therapy duration (lead) study: standard *versus* long treatment. A phase III trial in post-menopausal women with early breast cancer.

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Summary:

- Active since 6 April 2005
- Target accrual: 4050 patients

Objective:

- To compare the disease-free survival (DFS) in patients treated with 2/3 years of letrozole to that in patients treated with the 5 years of letrozole after treatment with tam for 2/3 years.

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Scheme: Arm A = patients pre-treated with tam for 2/3 years will receive letrozole 2.5 mg/day for 2–3 years. Total duration of early adjuvant endocrine therapy: 5 years
Arm B = patients pre-treated with tam for 2/3 years will receive letrozole 2.5 mg/day for an additional 5 years. Total duration of early adjuvant endocrine therapy: 7 years for patients pre-treated with 2 years of tam and 8 years for patients pre-treated with 3 years of tam

Update:
- Patients randomized: 373 as of 4 October 2006.
- Study ongoing.

Related Publications: None available

Topics:
- Aromatase inhibitors

Keywords: Adjuvant endocrine therapy, post-menopause, letrozole

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