ECTO, FM-B

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Country: Europe

Group: Fondazione Michelangelo Breast Cancer Group **(FM-B)**

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Title: European cooperative study of chemotherapy and surgery comparing adjuvant doxorubicin followed by CMF *versus* adjuvant doxorubicin/paclitaxel followed by CMF *versus* primary doxorubicin/paclitaxel followed by CMF in women with operable breast cancer and T > 2 cm.

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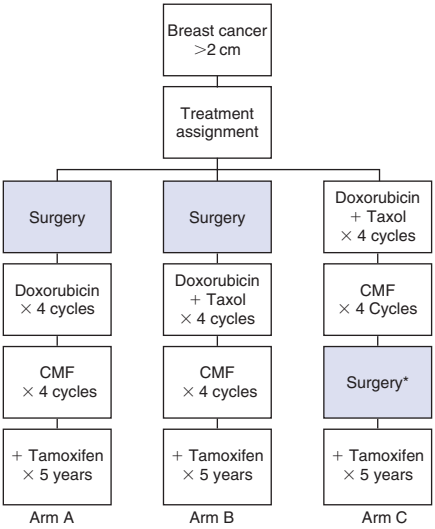
Summary:

- Opened in November 1996
- Target accrual: 1250 patients

Objectives:

- To evaluate whether 8 cycles of primary chemotherapy before adequate surgery of breast tumor and loco-regional radiotherapy + tamoxifen for 5 years improves the disease-free (DFS) and overall survival (OS) in women with operable breast carcinoma and T > 2 cm in diameter at diagnosis.
- To assess whether, in the postoperative arms, the addition of paclitaxel to doxorubicin before CMF improves DFS and OS in these patients.

Scheme:



* Whenever technically feasible: conservative surger plus breast irradiation

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Update:

- Enrolment completed as of May 2002; 1355 patients.

Related Publications:

Gianni L, Baselga J, Eiermann W *et al.*, for the ECTO Study Group. *European Cooperative Trial in Operable Breast Cancer (ECTO): improved freedom from progression (FFP) from adding paclitaxel (T) to doxorubicin (A) followed by Cyclophosphamide Methotrexate and Fluorouracil (CMF)*; Abstract ASCO 2005.

Gianni L, Baselga J, Eiermann W *et al*. Feasibility and tolerability of sequential doxorubicin/paclitaxel followed by cyclophosphamide, methotrexate, and fluorouracil and its effects on tumor response as preoperative therapy. *Clin Cancer Res* 2005; 11(24).

Topics:

None available

Keywords:

None available

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Title: European Cooperative Study of Primary Systemic Therapy in Women with Operable Breast Cancer and T > 2 cm.

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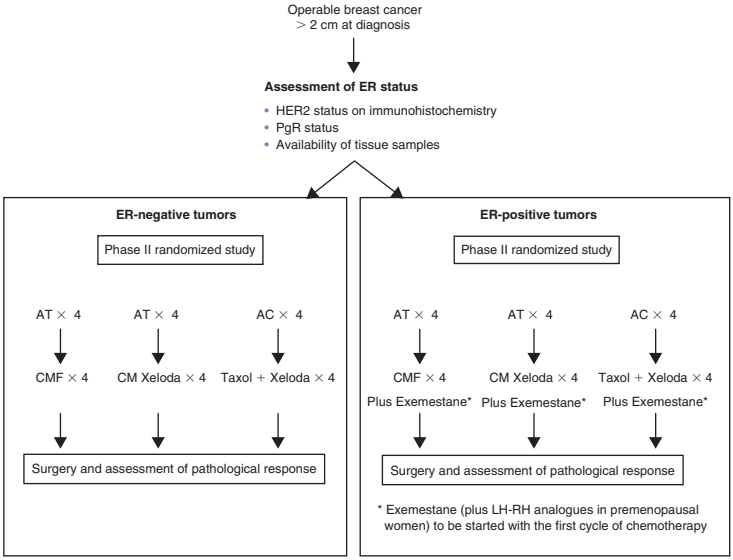
Summary:

- Opened in June 2005.
- *Overall study design*: This is a cooperative, multicenter, open-label trial, consisting of two parallel phase II randomized studies: Study 1, ER-negative tumors and Study 2, ER-positive tumors.
- Target accrual: 315 patients for Study 1 and 171 for Study 2.

Objectives:

- To assess the rate of pathological complete remission (pCR) in ER-negative (Study 1) and ER-positive (Study 2) operable breast cancer.
- To assess the rate of objective clinical remission (OR) after the first 4 cycles of each chemotherapy regimen and at the end of the entire primary program.
- To assess tolerability and safety of each proposed regimen.

Scheme:



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Update:	• 128 Patients enrolled as of September 2006
Related Publications:	None available
Topics:	None available
Keywords:	None available

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