ICCG

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Country: Europe, South America

Group: International Collaborative Cancer Group **(ICCG)**

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Title: Epirubicin plus tamoxifen *versus* tamoxifen alone in postmenopausal node-positive primary breast cancer.
C/4/87

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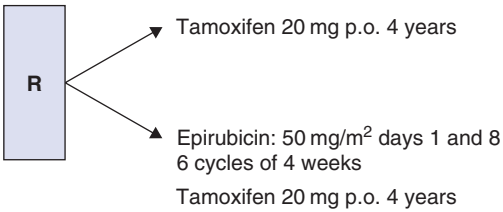
Summary:

- Closed in April 1998 (opened in September 1989)
- Target accrual: 694 patients

Objectives:

- Disease-free survival.
- Survival.

Scheme:



Update:

- Study closed April 1998; 648 patients randomized. Long-term follow-up ongoing.

Related Publications: Wils JA, Bliss JM, Marty M *et al.* Epirubicin plus tamoxifen *versus* tamoxifen alone in node positive postmenopausal patients with breast cancer: a randomized trial of the International Collaborative Cancer Group (ICCG). *J Clin Oncol* 1999; 17: 1–11.

Topics:

- Anthracyclines
- Tamoxifen
- Node-positive breast cancer
- Postmenopausal patients

Keywords: Adjuvant, anthracyclines, tamoxifen, node-positive breast cancer, postmenopausal

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Title: Adjuvant cyclophosphamide methotrexate and 5-fluorouracil (CMF) *versus* 5-fluorouracil, epirubicin and cyclophosphamide (FEC) in premenopausal node-positive primary breast cancer. (CMF/FEC N+)
C/2/84

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Summary:

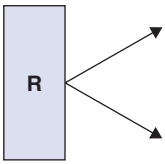
- First patient randomized: 1984

Objective:

- The primary aim of this study was to compare disease-free survival and overall survival in patients treated with CMF, with that observed in patients treated with FEC.

The study had two randomization schedules: CMF1/FEC1 (Non French centres) or CMF2/FEC2 (French Centres).

Scheme:



FEC 1
F – 600 m/m^2 i.v. days 1
E – 50 mg/m^2 i.v. days 1
C – 600 mg/m^2 i.v. days 1
8 cycles of 3 weeks

CMF 1
C – 100 mg/m^2 p.o. days 1–14
M – 40 mg/m^2 i.v. days 1–8
F – 600 mg/m^2 i.v. days 1–8
6 cycles of 4 weeks

OR

FEC 2
F – 600 mg/m^2 i.v. days 1 and 8
E – 50 mg/m^2 i.v. days 1
C – 600 mg/m^2 i.v. days 1 and 8
6 cycles of 4 weeks

CMF 2
C – 600 mg/m^2 i.v. days 1 and 8
M – 40 mg/m^2 i.v. days 1 and 8
F – 600 mg/m^2 i.v. days 1 and 8
6 cycles of 4 weeks

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Update:

- Study Status: Closed 1992. Active follow-up continues.
- Number of patients accrued: 759.

Related Publications:

Coombes RC, Bliss JM, Wils J *et al.* for the International Collaborative Cancer Group (ICCG). Adjuvant cyclophosphamide, methotrexate, 5-fluorouracil (CMF) *versus* 5-fluorouracil, epirubicin, cyclophosphamide (FEC) chemotherapy in premenopausal women with axillary node positive operable breast cancer: results of a randomised trial. *J Clin Oncol* 1996; 14: 35–45.

Topics:

- Node-positive breast cancer
- Premenopausal patients

Keywords:

Adjuvant, node-positive breast cancer, chemotherapy, premenopausal

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Title: Adjuvant cyclophosphamide, methotrexate and 5-fluorouracil (CMF) *versus* 5-fluorouracil, epirubicin and cyclophosphamide (FEC) in women with node-negative, poor-risk primary breast cancer.
C/6/89

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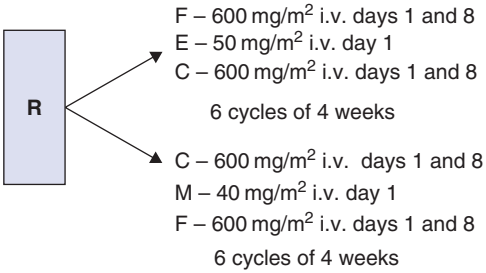
Summary:

- Opened in February 1990
- Target accrual: no target accrual but interim analysis after 600 patients

Objectives:

- Disease-free survival.
- Overall survival.

Scheme:



Update:

- Study closed to recruitment on 1 August 2000.
- Number of patients accrued: 950.
- Active follow-up continues.

Related Publications: None available

Topics:

- Node-negative breast cancer

Keywords: Adjuvant, node-negative breast cancer, chemotherapy

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Title: Adjuvant FEC50 *versus* FEC75 with or without the additional benefit of sequential hormone therapy (HT) in node-positive premenopausal primary breast cancer.
C/9/91

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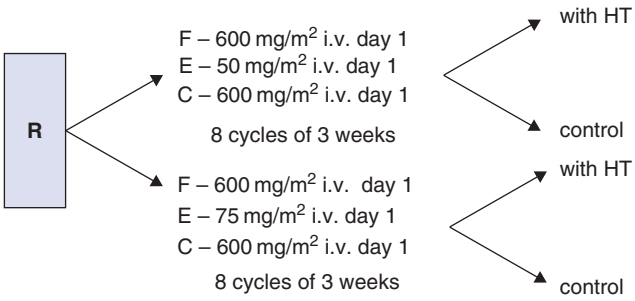
Summary:

- Opened in March 1992
- Target accrual: 720 patients

Objectives:

- Disease-free survival.
- Overall survival.

Scheme:



Update:

- Study closed to recruitment on 1 August 2000.
- Number of patients accrued: 785.
- Active follow-up continues.

Related Publications: None available

Topics:

- Node-positive breast cancer
- Premenopausal patients
- Hormonal therapy

Keywords: Adjuvant, chemotherapy, node-positive breast cancer, premenopausal, hormonal therapy

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Title: High-dose therapy with PBCS support in primary breast cancer.
C/10/92 – C/32/96

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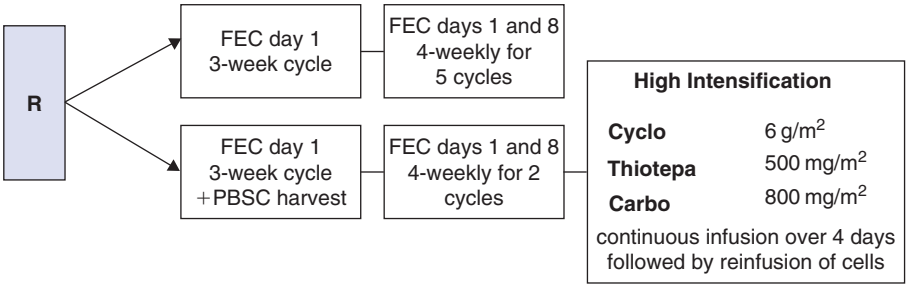
Summary:

- Opened in July 1993
- Target accrual: 230 patients

Objectives:

- Disease-free survival.
- Overall survival.

Scheme:



Update:

- Study closed to recruitment on 28 September 2001.
- Number of patients accrued: 281.
- Active follow-up continues.

Related Publications: Coombes RC, Bliss JM, Howell A *et al.*, on behalf of the International Collaborative Cancer Group. High dose chemotherapy and autologous stem cell transplantation as adjuvant therapy for primary breast cancer

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patients with four or more lymph nodes involved: long-term results of an International Randomised Trial. *Ann Oncol* 2005; 16(5): 726–734.

Topics:
- High-dose chemotherapy
- Node-positive breast cancer

Keywords: Adjuvant, high dose chemotherapy, node-positive breast cancer

https://doi.org/10.1017/S1470903106009242 Published online by Cambridge University Press

Title: Randomized double-blind trial in postmenopausal women with primary breast cancer who have received adjuvant tamoxifen for 2–3 years, comparing subsequent adjuvant exemestane treatment with further tamoxifen.
BIG 2-97/C/13/96

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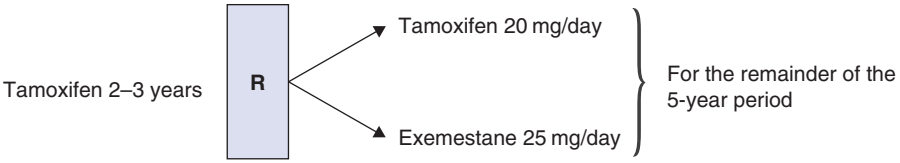
Summary:

- Opened in February 1998
- Target accrual: 1103 patients/arm

Objectives:

- To evaluate disease-free survival and overall survival in ER + or unknown breast cancer patients treated either with tamoxifen or with exemestane after having received adjuvant tamoxifen for 2–3 years.
- To evaluate the incidence of contralateral breast cancer and the general long-term tolerability of the regimens.
- To evaluate the tolerability of each regimen in terms of endometrial status, bone metabolism, lipid profile, coagulation profile and quality of life.

Scheme:



Quality of Life sub-Protocol

A study to compare the quality of life of those patients allocated to tamoxifen with those allocated to exemestane, with the aim of determining efficacy, toxicity and overall general health and well being. *(continued)*

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Endometrial Sub-Protocol

A study to assess endometrial ultrasound changes in postmenopausal patients receiving exemestane after 2–3 years of adjuvant tamoxifen compared to patients continuing on tamoxifen.

Bone Sub-Protocol

To compare bone mineral density (BMD) and metabolism in patients receiving exemestane with those receiving tamoxifen.

Update:

- The main study closed to recruitment on 28 February 2003.

  4740 patients recruited.

- *Quality of Life Study* – Closed to recruitment on 31 December 2001.

  581 patients recruited.

- *Endometrial Study* – Closed to recruitment on 31 August 2001.

  219 patients recruited.

- *Bone Study* – Closed to recruitment on 28 February 2003.

  206 patients recruited.

Related Publications:

Coombes RC *et al.* A randomized trial of exemestane after two to three years of tamoxifen therapy in postmenopausal women with primary breast cancer. *New Engl J Med* 2004; 350: 1081–1092.

Fallowfield L *et al.* Quality of Life in the Intergroup Exemestane Study: A randomized trial of exemestane *versus* continued tamoxifen after 2 to 3 years of tamoxifen in postmenopausal women with primary breast cancer. *J Clin Oncol* 2006; 24: 910–917.

Topics:

- Tamoxifen
- Aromatase inhibitors
- Postmenopausal patients

Keywords: Adjuvant, endocrine therapy, tamoxifen, aromatase inhibitors, postmenopausal

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Title: A multicentre-randomized trial of sequential epirubicin and docetaxel *versus* epirubicin in node-positive postmenopausal breast cancer patients.
C/14/96

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Summary:

- Opened in August 1997
- Target accrual: 800 patients

Primary Objectives:

- Disease-free survival.
- Overall survival.

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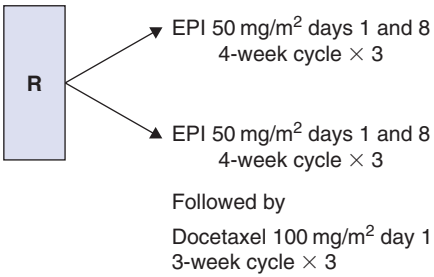
Secondary Objective:

- Incidence of thromboembolic events (selected centers).

Scheme:



Update:

- Study closed to recruitment in August 2005.
- Number of patients accrued: 804.
- Active follow-up continues.

Related Publications: None available

Topics:

- Postmenopausal
- Anthracyclines
- Taxanes
- Tamoxifen
- Node-positive breast cancer

Keywords: Adjuvant, postmenopausal, chemotherapy, anthracyclines, taxanes, tamoxifen, node-positive breast cancer

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Title: A phase III multicentre double-blind randomized trial of celecoxib *versus* placebo in primary breast cancer patients. An intergroup study from the International Collaborative Cancer Group and the German Breast Group (GBG).
BIG 1-03 – ICCG/C/20/01 – GBG 27
(see also study description under GBG)

Coordinator(s):

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Summary:

- Study due to open in October 2006
- Target accrual: 2590 patients

Primary Objective:

- To assess the disease-free survival (DFS) benefit of 2 years adjuvant therapy with the COX-2 inhibitor celecoxib compared with placebo in primary breast cancer patients.

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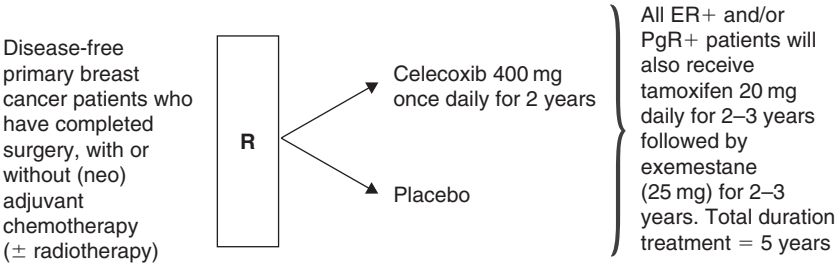
Secondary Objectives:

- To compare overall survival.
- To define the safety of adjuvant therapy with celecoxib in this patient population.
- To assess the DFS benefit of 2 years adjuvant celecoxib compared with placebo in hormone receptor (HR) positive disease.
- To compare the incidence of second primary breast cancers.
- In postmenopausal HR positive patients, to assess the tolerability of celecoxib with tamoxifen.
- To assess DFS benefit of 2 years adjuvant celecoxib compared with placebo in HR positive and in HR negative disease.

Scheme:



Update:
- Study will begin recruitment in October 2006.

Related Publications: None available

Topics:
- Aromatase inhibitors
- Celecoxib
- Tamoxifen

Keywords: Adjuvant, COX-2 inhibitors, aromatase inhibitors, tamoxifen

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