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Group: Spanish Breast Cancer Research Group (GEICAM)

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Website: www.geicam.org
**Title:** FAC versus CMF as adjuvant chemotherapy for operable breast cancer: a study by the GEICAM group.

**GEICAM/8701**

**Coordinator(s):** M. Martin  
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**Summary:**  
- Opened in November 1987  
- Accrual completed in December 1991 with 989 patients

**Objective:**  
- To determine the relative efficacy of doxorubicin versus methotrexate in combination with intravenous cyclophosphamide and 5-fluorouracil, as adjuvant chemotherapy for operable breast cancer.

**Scheme:**

Arm A: Cyclophosphamide 600 mg/m², methotrexate 60 mg/m², 5-fluorouracil 600 mg/m², day 1 every 3 weeks (6 cycles).  
Arm B: 5-Fluorouracil 500 mg/m² + doxorubicin 50 mg/m² + cyclophosphamide 500 mg/m², day 1 every 3 weeks (6 cycles).

Every 3 weeks

**Update:**  
- Presented (Poster) at the 37th ASCO Annual Meeting (2001).  
- Presented (Oral Presentation) at the 8th Spanish Society of Clinical Oncology Biannual Meeting (2001).


**Topics:**  
- Adjuvant treatment  
- Anthracyclines

**Keywords:** Adjuvant treatment, anthracyclines
Title: Phase III study of concomitant versus sequential chemohormonotherapy (EC plus tamoxifen) as adjuvant chemotherapy for node-positive postmenopausal women.
GEICAM/9401

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Summary:
• Opened in November 1994
• Accrual completed in June 2001 with 485 patients

Objective:
• To determine the best way to administer postsurgical chemotherapy plus tamoxifen (sequential versus concomitant) in node-positive postmenopausal breast cancer patients.

Scheme:
EC* + tamoxifen** 4 cycles
EC* → tamoxifen** 4 cycles

* EC: Epirubicin 75 mg/m² + cyclophosphamide 600 mg/m² day 1 every 3 weeks
** Tamoxifen: 20 mg/day for 5 years

Update:
• Final results were presented as oral communication at the 38th ASCO Annual Meeting (2002).

Related Publications:

Topics:
• Adjuvant treatment
• Tamoxifen
• Hormonal therapy

Keywords: Adjuvant treatment, tamoxifen, hormonal therapy
High-dose DICEP chemotherapy versus observation in metastatic breast cancer patients with monotopic disease responding to induction chemotherapy with paclitaxel plus epirubicin. Phase III GEICAM trial. GEICAM/9601

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Summary:
- Opened in December 1996
- Accrual completed in October 2000 with 52 patients

Objective:
- To determine the efficacy of high-dose consolidation DICEP chemotherapy (HD-DICEP) in prolonging progression-free survival (PFS) of chemotherapy responsive metastatic breast cancer (MBC) patients with monotopic disease.

Scheme:

Consolidation high-dose chemotherapy (DICEP) was according to the scheme of University of Washington Medical Center. This consisted of two courses of etoposide 150 mg/m² twice daily on days 1–3, cisplatin 75 mg/m² on days 1 and 5, and cyclophosphamide 2.25 mg/m² on days 4 and 5. The second course of consolidation chemotherapy was administered 6–8 weeks after the first.

Update: None available


Topics:
- High-dose chemotherapy
- Monotopic disease

Keywords: High-dose chemotherapy, monotopic disease
Title: Vinorelbine infusion over 96 hours in heavily pre-treated patients with metastatic breast cancer: a cooperative study by the GEICAM group. GEICAM/9702

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Summary:
- Opened in May 1996
- Accrual completed in March 1999 with 48 patients

Objective:
- To assess the activity of vinorelbine in a 96-hour continuous infusion in patients with metastatic breast cancer with poor prognosis.

Scheme:
Vinorelbine (8 mg/m²) injected slowly over 5–10 minutes on day 1, followed by 8 mg/m² on days 1–4 in continuous infusion.

Update:
None available

Related Publications:

Topics:
- Innovative schedules
- Multiple drug resistance

Keywords: Innovative schedules, multiple drug resistance
Title: Phase II trial of gemcitabine in combination with vinorelbine in patients with metastatic breast cancer resistant to anthracyclines. GEICAM/9704

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Summary:
• Opened in April 1998
• Accrual completed in December 2000 with 25 patients

Objective:
• To evaluate response rate and toxicity of a combination of gemcitabine and vinorelbine in patients with metastatic breast cancer.

Scheme:
All patients had previously received anthracyclines. Treatment consisted of gemcitabine 1200 mg/m² and vinorelbine 30 mg/m² on days 1 and 8 every 3 weeks.

Update:
• Presented (Proceedings) at the 38th ASCO Annual Meeting (2002).

Related Publications:

Topics:
• Multiple drug resistance
• Innovative schedules

Keywords:
Multiple drug resistance, innovative schedules
Title: A phase II trial for evaluation of sequential doxorubicin and docetaxel as first-line treatment in metastatic breast cancer. GEICAM/9801

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Summary:
• Opened in April 1997
• Accrual completed in December 1999 with 81 patients

Objective:
• To evaluate the efficacy and the toxicity profile of the sequential administration of doxorubicin and docetaxel as first-line chemotherapy in metastatic breast cancer.

Scheme:
Doxorubicin 75 mg/m² day 1 every 3 weeks (three courses) followed by docetaxel 100 mg/m² day 1 every 3 weeks (three courses).

Update:
• Presented (Poster) at the Conference of Federation of Spanish Societies of Oncology (2000).
• Presented (Poster) at the 19th Conference of Senology and Mammary Pathology (2000).
• Presented (Poster) at the 36th ASCO Annual Meeting (2000).
• Presented (Oral Presentation) at the 4th European Conference of Breast Cancer (2002).

Related Publications:
Results Published in Cancer Res Treat 2003; 77: 1–8.

Topics:
• Metastatic breast cancer
• Anthracyclines
• Taxanes

Keywords:
Metastatic breast cancer, anthracyclines, taxanes
Title: A multicenter phase III randomized trial comparing docetaxel with doxorubicin and cyclophosphamide (TAC) versus 5-fluorouracil with doxorubicin and cyclophosphamide (FAC) as adjuvant treatment of operable breast cancer patients with negative axillary lymph nodes.

TARGET 0 / GEICAM/9805

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Summary:
• Opened in June 1999
• Accrual completed in March 2003 with 1066 patients

Objective:
• To determine the relative efficacy and toxicity of docetaxel in combination with doxorubicin and cyclophosphamide (TAC) versus 5-fluorouracil in combination with doxorubicin and cyclophosphamide (FAC) as adjuvant chemotherapy for high-risk (St Gallen criteria) node-negative breast cancer.

Scheme:

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TAC* × 6 → tamoxifen*** to ER+
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FAC* × 6 → tamoxifen*** to ER+
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* Taxotere 75 mg/m² + doxorubicin 50 mg/m² day + cyclophosphamide 500 mg/m², day 1 every 3 weeks
** 5-Fluorouracil 500 mg/m² + doxorubicin 50 mg/m² + cyclophosphamide 500 mg/m², day 1 every 3 weeks
*** 20 mg/day for 5 years
Update:  • Presented (Poster) at the 27th Annual Symposium of the American Society of Breast Disease (ABSD) (2003).
  • Presented (Poster) at the 41st ASCO Annual Meeting (2005).

Related Publications: None available

Topics:  • Node-negative breast cancer
  • Anthracyclines
  • Taxanes

Keywords: Node-negative breast cancer, anthracyclines, taxanes
Title: A multicenter phase III randomized trial to compare the sequential and the concomitant administration of doxorubicin and docetaxel, as first-line chemotherapy treatment for metastatic breast disease. GEICAM/9903

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Summary:
• Opened in December 1999
• Accrual completed in December 2001 with 144 patients

Objective:
• To compare the hematological toxicity and efficacy of sequential versus concomitant administration of doxorubicin and docetaxel as metastatic breast cancer first-line treatment.

Scheme:

Randomization:
• Arm A: Sequential treatment with doxorubicin (A) (75 mg/m² q 21 days) and docetaxel (T) (100 mg/m² q 21 days). Patients with previous anthracyclines received A × 2 followed by T 3.4. Patients without previous anthracyclines received A × 3 followed by T × 3.
• Arm B: Concomitant treatment with A (50 mg/m²) plus T (75 mg/m²) q 21 days for 3 cycles, followed by 3 cycles of T (100 mg/m² q 21 days) in patients with previous anthracyclines, or by A plus T (50 mg/m² plus 75 mg/m²) q 21 days for 3 cycles in patients without previous anthracyclines.

Update:
• Presented (Proceedings) at the 38th ASCO Annual Meeting (2002).
• Presented (Oral Presentation) at the 39th ASCO Annual Meeting (2003).
• Presented (Oral Presentation) at the Spanish Society of Clinical Oncology Biannual Meeting (2003).

Related Publications:

Topics:
• Taxanes
• Anthracyclines
• Metastatic breast cancer

Keywords: Taxanes, anthracyclines, metastatic breast cancer
Title: Docetaxel plus gemcitabine administered every other week as first-line treatment for metastatic breast cancer.

GEICAM/9904

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Summary: • Opened in November 1999
• Accrual completed in November 2001 with 52 patients

Objective: • To assess the toxicity and efficacy of the combination of docetaxel and gemcitabine every 2 weeks as first-line therapy in metastatic breast cancer.

Scheme: Gemcitabine 2500 mg/m² i.v. – 60 minutes

Docetaxel 65 mg/m² i.v. – 60 minutes

Patients were scheduled to receive 10 cycles of chemotherapy unless evidence of progressive disease

• Presented (Poster) at the 38th ASCO Annual Meeting (2002).
• Presented at the 8th International Oncology Conference (St Gallen 2003).
• Presented (Proceedings) at the 39th ASCO Annual Meeting (2003).


Topics: • Metastatic breast cancer
• Taxanes
• Gemcitabine

Keywords: Metastatic breast cancer, taxanes, gemcitabine
**Title:** Weekly docetaxel as neo-adjuvant treatment in stage II and III breast cancer. 
*GEICAM/9905*

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**Summary:**  
- Opened in July 1999  
- Accrual completed in August with 56 patients

**Objective:**  
- Clinical and pathological response rate.

**Scheme:**

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Docetaxel  
40 mg/m^2 30 minutes i.v. q 7 days  
\( \times 6 \) infusions + 2 weeks rest = 1 cycle
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**Update:**  
- Presented (Poster) at the 23rd Annual San Antonio Breast Cancer Symposium (2000).  
- Presented (Oral Presentation) at the 4th European Conference of Breast Cancer (2002).


**Topics:**  
- Neo-adjuvant treatment  
- Taxanes

**Keywords:** Neo-adjuvant treatment, taxanes
Title: A multicenter phase III randomized trial comparing 5-fluorouracil with epirubicin and cyclophosphamide (FEC) versus 5-fluorouracil with epirubicin and cyclophosphamide (FEC) followed by weekly paclitaxel as adjuvant treatment of operable breast cancer patients with positive axillary lymph nodes.

GEICAM/9906

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Summary:
• Opened in December 1999
• Accrual completed in May 2002 with 1250 patients

Objective:
• To determine the relative efficacy and toxicity of 5-fluorouracil with epirubicin and cyclophosphamide (FEC) versus 5-fluorouracil with epirubicin and cyclophosphamide (FEC) followed by weekly paclitaxel as chemotherapy for operable breast cancer patients with positive axillary lymph nodes.
**Scheme:**

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- FEC* × 6 → tamoxifen*** to ER+
- FEC* × 4 → paclitaxel** × 8 → tamoxifen*** to ER+

* 5-Fluorouracil 600 mg/m² + epirubicin 90 mg/m² + cyclophosphamide 600 mg/m², day 1 every 3 weeks (6 cycles).

** 5-Flourouracil 600 mg/m² + epirubicin 90 mg/m² + cyclophosphamide 600 mg/m², day 1 every 3 weeks (4 cycles) followed by paclitaxel 100 mg/m² day 1 every week (8 weeks).

*** 20 mg/day for 5 years.

**Update:**
- First interim efficacy analysis presented (Oral Presentation) at the Spanish Society of Clinical Oncology Biannual Meeting (2003).
- First interim efficacy analysis presented (Poster) at the 26th Annual San Antonio Breast Cancer Symposium (2003).
- Presented (Oral Presentation) at the 28th Annual San Antonio Breast Cancer Symposium (2005).

**Related Publications:** None available

**Topics:**
- Adjuvant treatment
- Paclitaxel

**Keywords:** Adjuvant treatment, paclitaxel
Title: An open, multicenter randomized phase IV trial for the administration of pamidronate to breast cancer patients with bone metastatic disease. GEICAM/2000-01

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Summary: • Opened in May 2000
• Accrual completed in December 2002 with 150 patients

Objective: • To compare continuous administration of pamidronate for 18 months versus administration of aredia for 6 months followed by 6 months without treatment followed by administration of pamidronate for 6 months, to evaluate differences in time to first skeletal bone event in both arms.

Scheme: Randomization:
• Arm A: Pamidronate 90 mg every 3–4 weeks for 18 months.
• Arm B: Pamidronate 90 mg every 3–4 weeks for 6 months, then, 6 months at rest, followed by pamidronate 90 mg every 3–4 weeks for 6 months.


Related Publications: None available

Topics: • Bisphosphonates
• Symptomatic bone metastasis

Keywords: Bisphosphonates, symptomatic bone metastasis
Title: A randomized phase III treatment to compare the administration of vinorelbine versus vinorelbine plus gemcitabine in patients with metastatic breast cancer previously treated with anthracyclines and taxanes.

GEICAM/2000-04

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Summary: • Opened in December 2000
• Accrual completed in March 2005 with 252 patients

Objective: • To compare progression-free survival among treatment arms A and B in patients with metastatic breast cancer who have previously been treated with anthracyclines and taxanes.

Scheme: Randomization:
• Arm A: Vinorelbine 30 mg/m² days 1 and 8, every 3 weeks.
• Arm B: Vinorelbine 30 mg/m² days 1 and 8, every 3 weeks. Gemcitabine 1200 mg/m² days 1 and 8, every 3 weeks.

Patients will receive study treatment until progression of the disease or unacceptable toxicity.

Update: None available

Related Publications: None available

Topics: • Metastatic breast cancer
• Gemcitabine
• Innovative schedules

Keywords: Metastatic breast cancer, gemcitabine, innovative schedules
Title: Maintenance phase III/IV study for the administration of Caelyx versus no treatment, after induction chemotherapy for metastatic breast cancer disease. 
GEICAM/2001-01

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Summary: • Opened in June 2002
• Target: 154 patients

Objective:
• To evaluate time to disease progression after maintenance treatment with pegilated lyposomal doxorubicin (Caelyx) in patients with complete or partial response, or stable disease, versus non-maintenance treatment.

Scheme:
Arm A: Caelyx 40 mg/m² every 28 days × 6 cycles
Arm B: Observation

Update:
• Number of registered patients 254 as of March 2006.
• Accrual: 135 patients as of March 2006.

Related Publications: None available

Topics: • Induction chemotherapy
• Liposomal doxorubicin
• Metastatic breast cancer

Keywords: Induction chemotherapy, liposomal doxorubicin, metastatic breast cancer
Title: A multicenter, cross-over, randomized trial with exemestane versus anastrozole as first-line hormonal treatment of postmenopausal women with metastatic breast cancer disease and positive hormone receptors. GEICAM/2001-03

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Summary: • Opened in June 2001
• Accrual completed in March 2004 with 103 patients

Objective: • To evaluate objective response rate.

Scheme:
Arm A: Exemestane 25 mg/day p.o. QD, until disease progression
Arm B: Anastrozole 1 mg/day p.o. QD, until disease progression

After disease progression, the investigator will decide the treatment cross-over whenever deemed appropriate.

Update: None available
Related Publications: None available

Topics: • Aromatase inhibitors
• Hormonal therapy

Keywords: Aromatase inhibitors, hormonal therapy
Title: A multicenter, open-label randomized phase III trial for the administration of zoledronate to patients with advanced breast cancer disease and non-symptomatic bone metastasis.

GEICAM/2001-05

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Summary:
- Opened in April 2002
- Target: 224 patients

Objective:
- To assess zoledronate efficacy (combined with hormone therapy or chemotherapy) to delay bone metastasis symptoms in breast cancer patients with at least one single bone disease location.

Scheme: Randomization:
- Arm A: Zoledronate 4 mg every 3–4 weeks. Study treatment will be maintained until symptoms related to bone disease appear, or during 1 year (whichever occurs first).
- Arm B: Patients will not receive any treatment with bisphosphonates until symptoms related to bone disease appear, or during 1 year (whichever occurs first).

Update:
- Accrual: 89 patients as of March 2006.

Related Publications: None available

Topics:
- Bisphosphonates
- Non-symptomatic bone metastasis

Keywords: Bisphosphonates, non-symptomatic bone metastasis
Title: A multicenter phase II trial to evaluate the administration of gemcitabine with doxorubicin and paclitaxel (GAT) as neo-adjuvant treatment of stage III disease breast cancer patients.

GEICAM/2002-01

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Summary: • Opened in January 2003
• Accrual completed in July 2004 with 46 patients

Objective:
• To determine the rate of pathological complete response obtained with GAT combination of drugs in the neo-adjuvant treatment of stage III disease breast cancer patients.

Scheme:
• A: Doxorubicin 40 mg/m², day 1 every other week.
• T: Paclitaxel 150 mg/m² day 2 every other week.
• G: Gemcitabine 2000 mg/m² day 2 every other week.

This is defined a cycle. Each cycle is administered every 2 weeks, for a total of 6 cycles, prior to primary surgery of the breast.

Update:
• Presented (Poster) at the 27th Annual San Antonio Breast Cancer Symposium (2004).
• Presented (Proceedings) at the 41st ASCO Annual Meeting (2005).

Related Publications: None available

Topics:
• Neo-adjuvant treatment
• Gemcitabine
• Paclitaxel

Keywords: Neo-adjuvant treatment, gemcitabine, paclitaxel
Title: A phase II trial to evaluate the administration of doxorubicin with cyclophosphamide (AC) followed by weekly docetaxel (T) as neo-adjuvant treatment of stage II disease breast cancer patients.

GEICAM/2002-03

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Summary:

• Opened in January 2003
• Accrual completed in May 2004 with 63 patients

Objective:

• To determine the rate of pathological complete response (pCR) after induction treatment with doxorubicin and cyclophosphamide (AC) followed by weekly docetaxel in patients with operable breast cancer (stage II disease).

Scheme:

• AC: Doxorubicin 60 mg/m² plus cyclophosphamide 600 mg/m² day 1 every 3 weeks (4 cycles), followed by
• T: Docetaxel 36 mg/m² day 1, weekly, for 6 weeks.

A docetaxel cycle is defined as 6-weekly docetaxel infusions followed by 2 weeks without treatment (8 weeks). It is planned to administer 2 docetaxel cycles prior to primary breast surgery.

Update:

• Presented (Poster) at the 29th European Society for Medical Oncology (ESMO) (2004).
• Presented (Poster) at the 28th Annual San Antonio Breast Cancer Symposium (2005).

Related Publications:

None available
Topics:
- Docetaxel
- Neo-adjuvant treatment

Keywords: Docetaxel, neo-adjuvant treatment
Title: A multicenter, open-label, randomized phase III trial comparing six courses of FAC (fluorouracil, doxorubicin, cyclophosphamide) with four courses of FAC followed by 8-weekly administrations of Taxol in the adjuvant treatment of node-negative patients with operable breast cancer.

GEICAM/2003-02

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Summary:
• Opened in September 2003
• Target: 1920 patients

Objective:
• To determine the relative efficacy and toxicity of 5-fluorouracil with doxorubicin and cyclophosphamide (FAC) versus 5-fluorouracil with doxorubicin and cyclophosphamide (FAC) followed by weekly paclitaxel as chemotherapy for operable breast cancer patients with negative axillary lymph nodes.
**Scheme:**

Arm A: 5-Fluorouracil 500 mg/m² + doxorubicin 50 mg/m² + cyclophosphamide 500 mg/m², day 1 every 3 weeks (6 cycles).

Arm B: 5-Fluorouracil 500 mg/m² + doxorubicin 50 mg/m² + cyclophosphamide 500 mg/m², day 1 every 3 weeks (4 cycles) followed by paclitaxel 100 mg/m² day 1 every week (8 weeks).

**Update:**

- Accrual: 1100 patients as of March 2006.

**Related Publications:**

None available

**Topics:**

- Adjuvant treatment
- Node-negative breast cancer
- Paclitaxel

**Keywords:**

Adjuvant treatment, node-negative breast cancer, paclitaxel
Title: A multicenter, open-label, randomized phase III trial comparing epirubicin plus cyclophosphamide (EC) followed by docetaxel (T) with epirubicin plus docetaxel (ET) followed by capecitabine (X) in the adjuvant treatment of node-positive patients with operable breast cancer.

GEICAM/2003-10

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Summary:
• Opened in January 2004
• Target: 1382 patients

Objective:

• To determine the relative efficacy and toxicity epirubicin plus cyclophosphamide (EC) followed by docetaxel (T) with epirubicin plus docetaxel (ET) followed by capecitabine (X) in the adjuvant treatment of node-positive patients with operable breast cancer.

Scheme:

EC: Epirubicin/cyclophosphamide (90/600 mg/m^2) i.v. q 21 days × 4 courses followed by T: Docetaxel (100 mg/m^2) i.v. q 21 days × 4 course.

EC: Epirubicin/docetaxel (90/75 mg/m^2) i.v. q 21 days × 4 courses followed by X: Capecitabine (2500 mg/m^2) p.o. × 4 courses.
Update:  
- Accrual: 975 patients as of March 2006.

Related Publications:  
None available

Topics:  
- Adjuvant treatment
- Node-positive breast cancer
- Capecitabine
- Docetaxel

Keywords:  
Adjuvant treatment, node-positive breast cancer, capecitabine, docetaxel
Title: Open-label, no randomized, phases I–II of the treatment with Myocet/Taxotere/Herceptin as primary antineoplastic treatment in newly diagnosed breast cancer patients with HER2neu overexpression.

GEICAM/2003-03

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Summary: • Opened in February 2004
• Target: 9–24 patients

Objective:
• To assess the maximum tolerated dose of Myocet and Taxotere in combination with Herceptin.

Scheme: Open, single-arm, non-randomized phase I–II escalation trial in 3–6 patients/cohorts:
• Myocet: 50 mg/m², every 3 weeks, for 6 cycles.
• Taxotere: 60 mg/m², every 3 weeks, for 6 cycles.
• Herceptin: trastuzumab 4 mg/kg loading dose by i.v. infusion over 90 minutes followed by trastuzumab 2 mg/kg by i.v. infusion over 30 minutes weekly, every 3 weeks, for 6 cycles.

Update: • Accrual 19 patients as of March 2006. A phase II study is ongoing to assess efficacy of such a schedule of therapy.

Related Publications: None available

Topics: • Neo-adjuvant treatment
• HER2-positive patients
• Liposomal doxorubicin

Keywords: Neo-adjuvant treatment, HER2-positive patients, liposomal doxorubicin
Title: Phase IV.II clinical trial with the combination of pegylated liposomal doxorubicin, cyclophosphamide and trastuzumab in patients with metastatic breast cancer with overexpression HER2neu.

GEICAM/2004-05

Coordinator(s): M. Martin
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Summary: • Opened in January 2006
• Target: 49 patients

Objective: • To evaluate objective response rate.

Scheme:

Update: • Accrual: 1 patient as of March 2006.

Related Publications: None available

Topics: • Liposomal doxorubicin
• HER2-positive patients
• Metastatic breast cancer

Keywords: Liposomal doxorubicin, HER2-positive patients, metastatic breast cancer
Randomized clinical trial to compare the benefit of adding trastuzumab to the combination of capecitabine plus vinorelbine as second-line treatment for patients with locally advanced non-operable breast cancer or metastatic breast cancer with overexpression of HER2, who have progressed to a previous line of treatment for metastatic disease that included trastuzumab in combination with taxanes.

**GEICAM/2004-06**

**Coordinator(s):** M. Muñoz
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**Summary:**
- Opened in January 2006
- Target: 82 patients

**Objective:**
- To evaluate objective response rate.

**Scheme:**
- Arm A: VX
- Arm B: HVX

VX: Vinorelbine 25 mg/m² i.v. infusion days 1 and 8, every 3 weeks, followed by capecitabine 825 mg/m² p.o. twice a day for 14 days, followed by a 7 days rest period, every 3 weeks.

H VX: Trastuzumab 4 mg/kg loading dose by i.v. infusion over 90 minutes followed by trastuzumab 2 mg/kg by i.v. infusion over 30 minutes weekly. Vinorelbine 25 mg/m² i.v. infusion days 1 and 8, every 3 weeks, followed capecitabine 825 mg/m² p.o. twice a day for 14 days, followed by a 7 days rest period, every 3 weeks.

**Update:**
- Accrual: 3 patients as of March 2006.

**Related Publications:** None available

**Topics:**
- Metastatic breast cancer
- HER2-positive patients

**Keywords:** Metastatic breast cancer, HER2-positive patients
**Title:** Phase IV.II clinical trial, multicenter, for administration of capecitabine concomitant to radiotherapy in patients with locally advanced breast cancer and HER2neu negatives.

**GEICAM/2005-01**

**Coordinator(s):** M. de las Heras  
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**Summary:**  
- Initiation of inclusion in July 2006  
- Target: 46 patients

**Objective:**  
- To determine the rate of pathological complete response.

**Scheme:**

Locally advanced breast cancer  
HER2 negative after mastectomy

Radiotherapy + capecitabine

Surgery

Pathological response

X: 825 mg/m² twice a day for 25 days, concomitant to radiotherapy.

**Update:** None available
Related Publications: None available

Topics:  
- Radiotherapy  
- Objective response rate  
- Loco-regional relapse

Keywords: Radiotherapy, objective response rate, loco-regional relapse
Title: Phase IV.III, multicenter, open, randomized treatment study to evaluate the efficacy of maintenance therapy with capecitabine after standard chemotherapy with anthracyclines in patients with metastatic breast cancer.

GEICAM/2005-04

Coordinator(s): A. Barnadas
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Summary:
• Initiation of inclusion in May 2006
• Target: 128 patients

Objective:
• To evaluate time to disease progression after maintenance treatment with capecitabine (Xeloda) in patients with complete or partial response, or stable disease, versus non-maintenance treatment.

Scheme:

X: 800 mg/m² twice a day for 14 days, followed by a 7 days rest period, for 8 cycles.

Update: None available
Related Publications: None available

Topics:
- Metastatic breast cancer
- Maintenance treatment
- Capecitabine

Keywords: Metastatic breast cancer, maintenance treatment, capecitabine