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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:

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R

EC* + tamoxifen** 4 cycles

EC* → tamoxifen** 4 cycles
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* 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).


Topics: • Adjuvant treatment
• Tamoxifen
• Hormonal therapy

Keywords: Adjuvant treatment, tamoxifen, hormonal therapy
Title: 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:  
Metastatic breast cancer with monotopic disease  
Chemotherapy with paclitaxel 200 mg/m² i.v. plus epirubicin 90 mg/m² i.v. both on day 1 every 3 weeks

Complete response or a partial response amenable to irradiation

R

Arm A: DICEP

Arm B: Observation

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.

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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


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+

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 × 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).


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

Update:
• Presented (Poster) at the 24th Annual San Antonio Breast Cancer Symposium (2001).
• 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).

Related Publications:

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:
\[
\text{Docetaxel} \\
40 \text{mg/m}^2 \text{ 30 minutes i.v. q 7 days} \\
\times 6 \text{ infusions} + 2 \text{ weeks rest} = 1 \text{ cycle}
\]

Update:
• Presented (Poster) at the 23rd Annual San Antonio Breast Cancer Symposium (2000).
• Presented (Proceedings) at the 37th ASCO Annual Meeting (2001).
• Presented (Oral Presentation) at the 4th European Conference of Breast Cancer (2002).

Related Publications:

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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R
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- **FEC** × 6 \(\rightarrow\) tamoxifen*** to ER+
- **FEC** × 4 \(\rightarrow\) paclitaxel** × 8 \(\rightarrow\) tamoxifen*** to ER+

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

** 5-Fluorouracil 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 liposomal 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:  

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/m²) i.v. q 21 days × 4 courses followed by T: Docetaxel (100 mg/m²) i.v. q 21 days × 4 course.

EC: Epirubicin/docetaxel (90/75 mg/m²) i.v. q 21 days × 4 courses followed by X: Capecitabine (2500 mg/m²) 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
Servicio de Oncología Médica
Hospital Clínico U. San Carlos
Professor Martin Lagos s/n
28040 MADRID
SPAIN

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
Title: 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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Villarroel, 170
08036 BARCELONA
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Summary:
• Opened in January 2006
• Target: 82 patients

Objective:
• To evaluate objective response rate.

Scheme:

<table>
<thead>
<tr>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HVX: 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.</td>
</tr>
</tbody>
</table>

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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M. Martín
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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:

R

Observation

8 Cycles

21 days = 1 cycle

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

Update: None available
None available

- Metastatic breast cancer
- Maintenance treatment
- Capecitabine

Metastatic breast cancer, maintenance treatment, capecitabine