GEICAM

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Country: Spain

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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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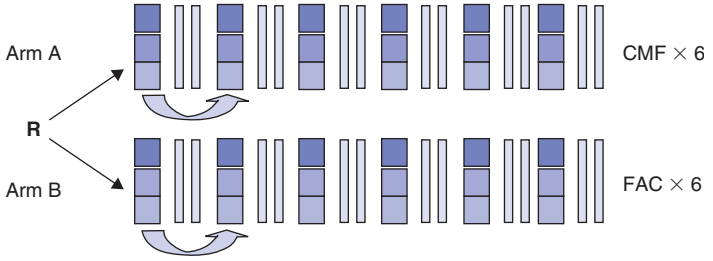
Summary:

- 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/m^2, methotrexate 60 mg/m^2, 5-fluorouracil 600 mg/m^2, day 1 every 3 weeks (6 cycles).
Arm B: 5-Fluorouracil 500 mg/m^2 + doxorubicin 50 mg/m^2 + cyclophosphamide 500 mg/m^2, day 1 every 3 weeks (6 cycles).

Update:

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

Related Publications: Results Published in *Ann Oncol* 2003; 14 (6): 833–842.

Topics:

- Adjuvant treatment
- Anthracyclines

Keywords: Adjuvant treatment, anthracyclines

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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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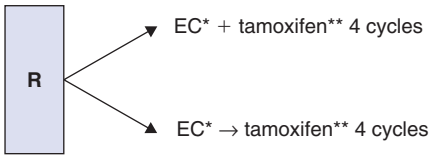
Summary:

- 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: Epirubicin 75 mg/m^2 + cyclophosphamide 600 mg/m^2 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: Results published in *Ann Oncol* 2004; 15 (1): 79–87.

Topics:

- Adjuvant treatment
- Tamoxifen
- Hormonal therapy

Keywords: Adjuvant treatment, tamoxifen, hormonal therapy

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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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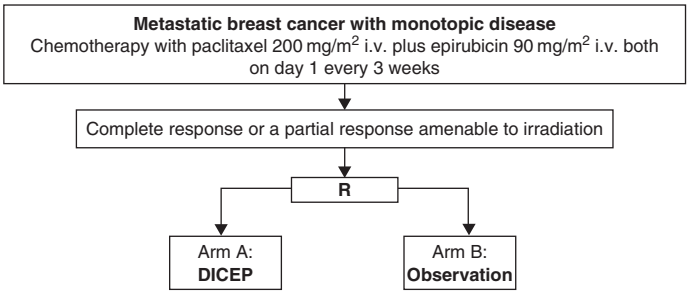
Summary:

- 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:



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/m^2 twice daily on days 1–3, cisplatin 75 mg/m^2 on days 1 and 5, and cyclophosphamide 2.25 mg/m^2 on days 4 and 5. The second course of consolidation chemotherapy was administered 6–8 weeks after the first.

Update: None available

Related Publications: Results published in *Revista de Oncología* 2003; 5: 148–155.

Topics:

- High-dose chemotherapy
- Monotopic disease

Keywords: High-dose chemotherapy, monotopic disease

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

Title: Vinorelbine infusion over 96 hours in heavily pre-treated patients with metastatic breast cancer: a cooperative study by the GEICAM group. **GEICAM/9702**

Coordinator(s): C. Jara
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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/m^2) injected slowly over 5–10 minutes on day 1, followed by 8 mg/m^2 on days 1–4 in continuous infusion.

Update: None available

Related Publications: Results published in *Clin Breast Cancer* 2003; 3 (6): 399–404.

Topics:

- Innovative schedules
- Multiple drug resistance

Keywords: Innovative schedules, multiple drug resistance

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

Title: Phase II trial of gemcitabine in combination with vinorelbine in patients with metastatic breast cancer resistant to anthracyclines.
GEICAM/9704

Coordinator(s): F. Lobo
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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/m^2 and vinorelbine 30 mg/m^2 on days 1 and 8 every 3 weeks.

Update:

- Presented (Proceedings) at the 38th ASCO Annual Meeting (2002).

Related Publications: Results published in *Clin Breast Cancer* 2003; 4 (1): 46–50.

Topics:

- Multiple drug resistance
- Innovative schedules

Keywords: Multiple drug resistance, innovative schedules

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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/m^2 day 1 every 3 weeks (three courses) followed by docetaxel 100 mg/m^2 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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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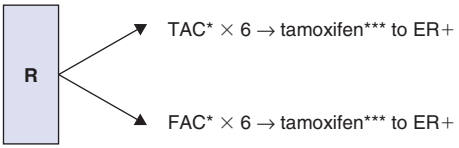
Summary:

- 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:



* Taxotere 75 mg/m^2 + doxorubicin 50 mg/m^2 day + cyclophosphamide 500 mg/m^2, day 1 every 3 weeks

** 5-Fluorouracil 500 mg/m^2 + doxorubicin 50 mg/m^2 + cyclophosphamide 500 mg/m^2, day 1 every 3 weeks

*** 20 mg/day for 5 years

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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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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/m^2 q 21 days) and docetaxel (T) (100 mg/m^2 q 21 days). Patients with previous anthracyclines received A $\times$ 2 followed by T 3 4. Patients without previous anthracyclines received A $\times$ 3 followed by T $\times$ 3.
- Arm B: Concomitant treatment with A (50 mg/m^2) plus T (75 mg/m^2) q 21 days for 3 cycles, followed by 3 cycles of T (100 mg/m^2 q 21 days) in patients with previous anthracyclines, or by A plus T (50 mg/m^2 plus 75 mg/m^2) 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: Results published in *J Clin Oncol* 2004; 22 (13): 2587–2593.

Topics:

- Taxanes
- Anthracyclines
- Metastatic breast cancer

Keywords: Taxanes, anthracyclines, metastatic breast cancer

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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

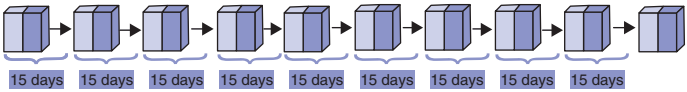
Objective:

- 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/m^2 i.v. – 60 minutes

Docetaxel 65 mg/m^2 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: Results published in *Sem Oncol* 2004; 31 (2 Suppl 4): 20–24.

Topics:

- Metastatic breast cancer
- Taxanes
- Gemcitabine

Keywords: Metastatic breast cancer, taxanes, gemcitabine

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

Title: Weekly docetaxel as neo-adjuvant treatment in stage II and III breast cancer.
GEICAM/9905

Coordinator(s): L. García Estévez
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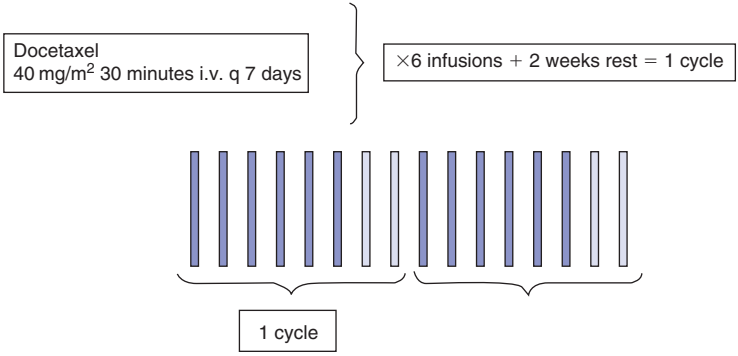
Summary:

- Opened in July 1999
- Accrual completed in August with 56 patients

Objective:

- Clinical and pathological response rate.

Scheme:



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: Results published in *Clin Cancer Res* 2003; 9: 686–692.

Topics:

- Neo-adjuvant treatment
- Taxanes

Keywords: Neo-adjuvant treatment, taxanes

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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.

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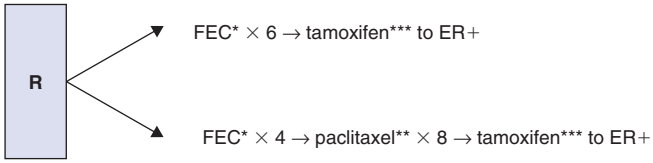
Scheme:



* 5-Fluorouracil 600 mg/m^2 + epirubicin 90 mg/m^2 + cyclophosphamide 600 mg/m^2, day 1 every 3 weeks (6 cycles).

** 5-Flurouracil 600 mg/m^2 + epirubicin 90 mg/m^2 + cyclophosphamide 600 mg/m^2, day 1 every 3 weeks (4 cycles) followed by paclitaxel 100 mg/m^2 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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.

Update:

- Presented (Poster) at the 28th Annual San Antonio Breast Cancer Symposium (2005).

Related Publications: None available

Topics:

- Bisphosphonates
- Symptomatic bone metastasis

Keywords: Bisphosphonates, symptomatic bone metastasis

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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/m^2 days 1 and 8, every 3 weeks.
- Arm B: Vinorelbine 30 mg/m^2 days 1 and 8, every 3 weeks. Gemcitabine 1200 mg/m^2 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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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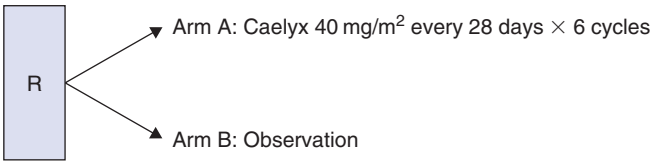
Summary:

- 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:



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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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

Coordinator(s): A. Llombart
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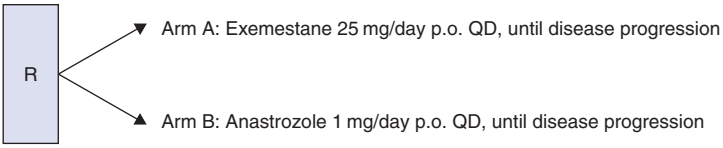
Summary:

- 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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/m^2, day 1 every other week.
- T: Paclitaxel 150 mg/m^2 day 2 every other week.
- G: Gemcitabine 2000 mg/m^2 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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/m^2 plus cyclophosphamide 600 mg/m^2 day 1 every 3 weeks (4 cycles), followed by
- T: Docetaxel 36 mg/m^2 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

Topics:
- Docetaxel
- Neo-adjuvant treatment

Keywords: Docetaxel, neo-adjuvant treatment

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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:

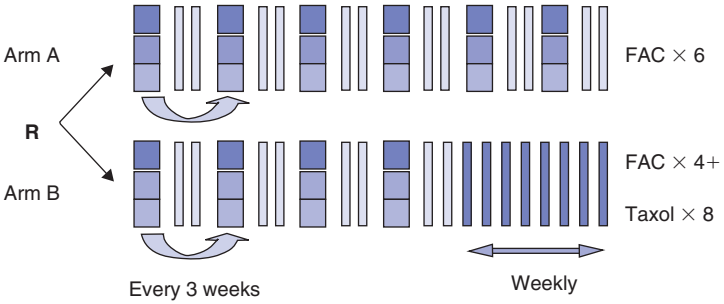
- Opened in September 2003
- Target: 1920 patients

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.

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

Scheme:



Arm A: 5-Fluorouracil 500 mg/m^2 + doxorubicin 50 mg/m^2 + cyclophosphamide 500 mg/m^2, day 1 every 3 weeks (6 cycles).

Arm B: 5-Fluorouracil 500 mg/m^2 + doxorubicin 50 mg/m^2 + cyclophosphamide 500 mg/m^2, day 1 every 3 weeks (4 cycles) followed by paclitaxel 100 mg/m^2 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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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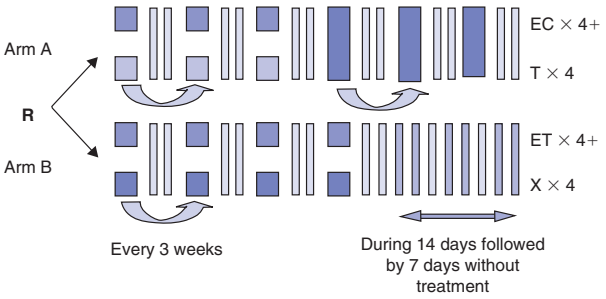
Summary:

- 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.

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

Title: Open-label, no randomized, phases I–II of the treatment with Myocet/Taxotere/Herceptin as primary antineoplasic 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/m^2, every 3 weeks, for 6 cycles.
- Taxotere: 60 mg/m^2, 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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

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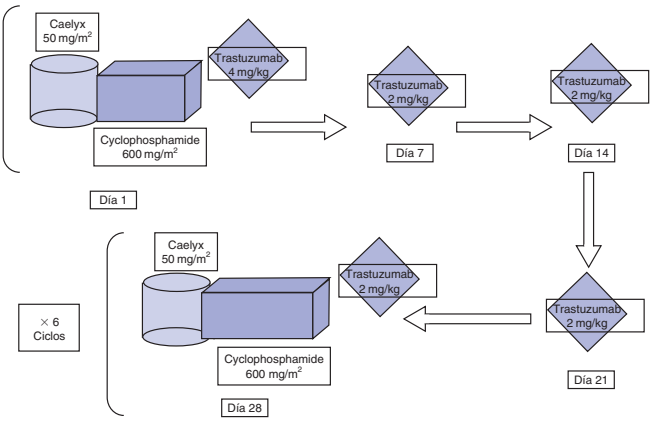
Summary:

- 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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

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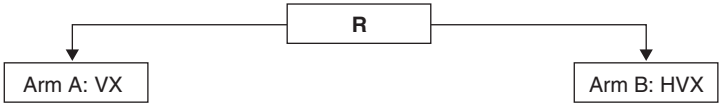
Summary:

- Opened in January 2006
- Target: 82 patients

Objective:

- To evaluate objective response rate.

Scheme:



VX: Vinorelbine 25 mg/m^2 i.v. infusion days 1 and 8, every 3 weeks, followed by capecitabine 825 mg/m^2 p.o. twice a day for 14 days, followed by a 7 days rest period, every 3 weeks.
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/m^2 i.v. infusion days 1 and 8, every 3 weeks, followed capecitabine 825 mg/m^2 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

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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

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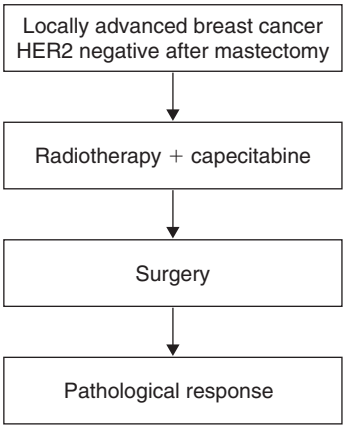
Summary:

- Initiation of inclusion in July 2006
- Target: 46 patients

Objective:

- To determine the rate of pathological complete response.

Scheme:



X: 825 mg/m^2 twice a day for 25 days, concomitant to radiotherapy.

Update: None available

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

Related Publications:	None available
Topics:	• Radiotherapy • Objective response rate • Loco-regional relapse
Keywords:	Radiotherapy, objective response rate, loco-regional relapse

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

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

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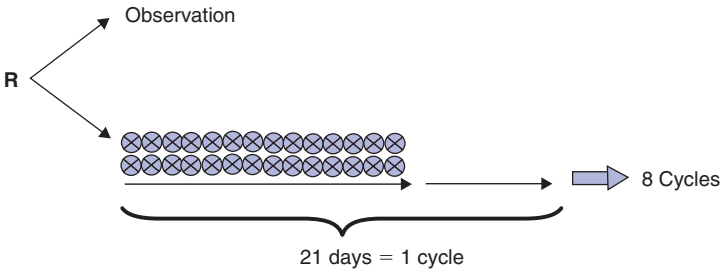
Summary:

- 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/m^2 twice a day for 14 days, followed by a 7 days rest period, for 8 cycles.

Update: None available

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press

Related Publications:	None available
Topics:	• Metastatic breast cancer • Maintenance treatment • Capecitabine
Keywords:	Metastatic breast cancer, maintenance treatment, capecitabine

https://doi.org/10.1017/S1470903106009175 Published online by Cambridge University Press