

# Clinical trials of Anthracyclines based regimen for advanced breast cancer (metastatic) in all type of patients

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## 1 chemotherapy comparison

| Trial  | Treatments   | Patients               | Trials design and methods |
|--|--|------------------------|---------------------------|
| <b>CNF vs CAF</b>                                    |  |                        |                           |
| Stewart , 1997<br>n=121/128<br>follow-up:            | CNF intravenous cyclophosphamide 500 mg/m2 plus fluorouracil 500 mg/m2 + mitoxantrone 10 mg/m2 every 3 weeks<br>versus<br>CAF intravenous cyclophosphamide 500 mg/m2 plus fluorouracil 500 mg/m2 + doxorubicin (Adriamycin) 50 mg/m2 every 3 weeks | advanced breast cancer | open                      |
| <b>CAF vs CMFVP</b>                                  |  |                        |                           |
| Smalley , 1983<br>n=NA<br>follow-up:                 | cyclophosphamide, doxorubicin, and 5-fluorouracil (CAF)<br>versus<br>cyclophosphamide, methotrexate, 5-fluorouracil, vincristine, and prednisone (CMFVP)   | -                      |                           |
| <b>MV vs FAC/FEC</b>                                 |  |                        |                           |
| Namer , 2001<br>n=NA<br>follow-up:                   | mitoxantrone+vinorelbine (MV)<br>versus<br>5-fluorouracil+cyclophosphamide+either doxorubicin or epirubicin (FAC/FEC)  | -                      |                           |
| <b>FAC vs FEC</b>                                    |  |                        |                           |
| French Epirubicin Study , 1988<br>n=NA<br>follow-up: | fluorouracil, 500 mg/m2; cyclophosphamide, 500 mg/m2; and either epirubicin<br>versus<br>doxorubicin   | -                      |                           |
| Italian Study , 1988<br>n=NA<br>follow-up:           | fluorouracil, epirubicin, and cyclophosphamide<br>versus<br>fluorouracil, doxorubicin, and cyclophosphamide  | -                      |                           |

## References

### Stewart, 1997:

Stewart DJ, Evans WK, Shepherd FA, Wilson KS, Pritchard KI, Trudeau ME, Wilson JJ, Martz K Cyclophosphamide and fluorouracil combined with mitoxantrone versus

doxorubicin for breast cancer: superiority of doxorubicin. J Clin Oncol 1997;15:1897-905 [9164200]

**Smalley, 1983:**

Smalley RV, Lefante J, Bartolucci A, Carpenter J, Vogel C, Krauss S A comparison of cyclophosphamide, adriamycin, and 5-fluorouracil (CAF) and cyclophosphamide, methotrexate, 5-fluorouracil, vincristine, and prednisone (CMFVP) in patients with advanced breast cancer. Breast Cancer Res Treat 1983;3:209-20 [6688538]

**Namer, 2001:**

Namer M, Soler-Michel P, Turpin F, Chinet-Charrot P, de Gislain C, Pouillart P, Delozier T, Luporsi E, Etienne PL, Schraub S, Eymard JC, Serin D, Ganem G, Calais G, Maillart P, Colin P, Trillet-Lenoir V, Prevost G, Tigaud D, Clavre P, Marti P, Romieu G, Results of a phase III prospective, randomised trial, comparing mitoxantrone and vinorelbine (MV) in combination with standard FAC/FEC in front-line therapy of metastatic breast cancer. Eur J Cancer 2001;37:1132-40 [11378344]

**French Epirubicin Study , 1988:**

A prospective randomized phase III trial comparing combination chemotherapy with cyclophosphamide, fluorouracil, and either doxorubicin or epirubicin. French Epirubicin Study Group. J Clin Oncol 1988;6:679-88 [2895801]

**Italian Study, 1988:**

Phase III randomized study of fluorouracil, epirubicin, and cyclophosphamide v fluorouracil, doxorubicin, and cyclophosphamide in advanced breast cancer: an Italian multicentre trial. Italian Multicentre Breast Study with Epirubicin. J Clin Oncol 1988;6:976-82 [2897433]

## 2 initial chemotherapy

| Trial                              | Treatments   | Patients | Trials design and methods |
|------------------------------------|--|----------|---------------------------|
| <b>sequentially vs combination</b> |  |          |                           |
| ANZBC , 1986<br>n=NA<br>follow-up: | treatment sequences, doxorubicin plus cyclophosphamide (AC) followed on failure by tamoxifen (TAM), and TAM followed by AC versus combined modality chemo-endocrine therapy (TAM plus AC). | -        |                           |

## References

**ANZBC, 1986:**

A randomized trial in postmenopausal patients with advanced breast cancer comparing endocrine and cytotoxic therapy given sequentially or in combination. The Australian and New Zealand Breast Cancer Trials Group, Clinical Oncological Society of Australia. J Clin Oncol 1986;4:186-93 [2868074]

## 3 more cycles of chemotherapy

| Trial  | Treatments | Patients | Trials design and methods |
|--|------------|----------|---------------------------|
| <b>FEC x 24 + tamoxifen vs FEC x 8 + tamoxifen</b> |            |          |                           |

continued...

| Trial                           | Treatments   | Patients | Trials design and methods |
|---------------------------------|--|----------|---------------------------|
| Ejlertsen<br>n=NA<br>follow-up: | cyclophosphamide, epirubicin and<br>5-fluorouracil (CEF) once every 3 weeks for a<br>maximum of 18 months<br>versus<br>identical chemotherapy for a maximum of 6<br>months | -        |                           |

## References

### Ejlertsen, :

Ejlertsen B, Pfeiffer P, Pedersen D, Mouridsen HT, Rose C, Overgaard M, Sandberg E, Kristensen B Decreased efficacy of cyclophosphamide, epirubicin and 5-fluorouracil in metastatic breast cancer when reducing treatment duration from 18 to 6 months. *Eur J Cancer* 1993;29A:527-31 [[8435205](#)]

## 4 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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