

Clinical trials of Taxanes for advanced breast cancer (metastatic) in all type of patients

TrialResults-center www.trialresultscenter.org

1 A CLASSER

| Trial | Treatments | Patients | Trials design and methods |
|--------------------------------------|---|----------|---------------------------|
| vs | | | |
| AGO , 1998 n=NA follow-up: | - | - | |
| EU-1 , 2004 n=NA follow-up: | - | - | |
| Lyman n=NA follow-up: | - | - | |
| Nabholtz n=NA follow-up: | - | - | |
| TRAVIOTA n=NA follow-up: | - | - | |
| Yardley , 2009 n=NA follow-up: | weekly docetaxel versus liposomal doxorubicin | - | |

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von Minckwitz G, Kuhn W, Thomssen C, Untch M, Bauknecht T, Eidtmann D, et al. Phase III trial comparing epirubicin/paclitaxel vs epirubicin/cyclophosphamide as first line treatment in metastatic breast cancer: preliminary results of a German AGO trial. European Journal of Cancer 1998;34 (Supplement 5):S90.

EU-1, 2004:

Heidemann E, Minckwitz GV, Hollander N, Souchon R, Clemens M, Mahike M, et al. Mitoxantrone plus docetaxel vs single agent mitoxantrone in metastatic breast cancer (MBC): results of a multicenter randomized trial. Proceedings of American Society of Clinical Oncology; 2004. 2004; Vol. 22, No 14S:637. NCT00002544. Mitoxantrone with or without docetaxel in treati

Lyman, 0:

Nabholtz, 0:

TRAVIOTA, 0:

Yardley, 2009:

Yardley, DA A phase II randomized crossover study of liposomal doxorubicin versus weekly docetaxel in the first-line treatment of women with metastatic breast cancer. Clin. Breast Cancer 2009;9:247-52 [[19933081](#)] [10.3816/CBC.2009.n.042](#)

2 nab-paclitaxel

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|---------------------------|
| nab-paclitaxel vs docetaxel | | | |
| Gradishar , 2009 [NCT00274456] n=302 follow-up: | weekly and every 3 week (q3w) nab-paclitaxel versus docetaxel | first-line treatment in patients with MBC | |
| nab-paclitaxel + gemcitabine or carboplatin vs gemcitabine or carboplatin | | | |
| tnAcity ongoing [NCT01881230] n=NA follow-up: | Weekly Nab-Paclitaxel in Combination With Gemcitabine or Carboplatin versus Gemcitabine or Carboplatin | - | |
| nab-paclitaxel +gencotabine vs gemcitabine | | | |
| Roy , 2008 [NCT00110084] n=50 follow-up: | - | patients with previously untreated metastatic breast cancer | |

References

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Gradishar WJ, Krasnojon D, Cheporov S, Makhson AN, Manikhas GM, Clawson A, Bhar P Significantly longer progression-free survival with nab-paclitaxel compared with docetaxel as first-line therapy for metastatic breast cancer. J Clin Oncol 2009;27:3611-9 [[19470941](#)]

Dranitsaris G, Coleman R, Gradishar W nab-Paclitaxel weekly or every 3 weeks compared to standard docetaxel as first-line therapy in patients with metastatic breast cancer: an economic analysis of a prospective randomized trial. Breast Cancer Res Treat 2010;119:717-24 [[19495958](#)]

Gradishar WJ, Krasnojon D, Cheporov S, Makhson AN, Manikhas GM, Clawson A, Bhar P, McGuire JR, Iglesias J Phase II trial of nab-paclitaxel compared with docetaxel as first-line chemotherapy in patients with metastatic breast cancer: final analysis of overall survival. Clin Breast Cancer 2012;12:313-21 [[22728026](#)]

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Aapro M, Tjulandin S, Bhar P, Gradishar W Weekly nab-paclitaxel is safe and effective in >65 years old patients with metastatic breast cancer: a post-hoc analysis. Breast 2011;20:468-74 [[21843943](#)]

tnAcity, :

Roy, 2008:

Roy V, LaPlant BR, Gross GG, Bane CL, Palmieri FM Phase II trial of weekly nab (nanoparticle albumin-bound)-paclitaxel (nab-paclitaxel) (Abraxane) in combination with gemcitabine in patients with metastatic breast cancer (N0531). Ann Oncol 2009;20:449-53 [[19087987](#)]

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Roy V, LaPlant BR, Gross GG, et al. NCCTG phase II trial N0531 of weekly nab-paclitaxel (nab-p) in combination with gemcitabine (gem) in patients with metastatic breast cancer (MBC). [Abstract] J Clin Oncol 25 (Suppl 18): A-1048, 2007.

3 taxanes alone

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|---------------------------|
| paclitaxel vs capecitabine | | | |
| Talbot , 2002 n=NA follow-up: | i.v. paclitaxel (175 mg m(-2), versus 3-week cycles of intermittent oral capecitabine (1255 mg m(-2) twice daily, days 1-14, | - | |
| paclitaxel vs cisplatin, etoposide | | | |
| TOG , 2005 n=NA follow-up: | - | - | |
| paclitaxel vs CMFP | | | |
| ANZ TITG , 1999 n=NA follow-up: | paclitaxel 200 mg/m(2) intravenously (IV) over 3 hours for eight cycles (24 weeks) versus standard cyclophosphamide 100 mg/m(2)/d orally on days 1 to 14, methotrexate 40 mg/m(2) IV on days 1 and 8, fluorouracil 600 mg/m(2) IV on days 1 and 8, and prednisone 40 mg/m(2)/d orally on days 1 to 14 (CMFP) for six cycles (24 weeks) with epirubicin re | front-line therapy in untreated metastatic breast cancer | |
| docetaxel vs doxorubicin | | | |
| 303 Study Group , 1999 n=161/165 follow-up: | intravenous infusion of docetaxel 100 mg/m(2) every 3 weeks for a maximum of seven treatment cycles. versus intravenous infusion of doxorubicin 75 mg/m(2) every 3 weeks for a maximum of seven treatment cycles. | patients with metastatic breast cancer who had received previous alkylating agent-containing chemotherapy | |
| paclitaxel vs doxorubicin | | | |
| ECOG E1193 (B) , 2003 n=NA follow-up: | paclitaxel (175 mg/m(2)/24 h), versus doxorubicin (60 mg/m(2)), | patients with metastatic breast cancer | |
| EORTC 10923 , 2000 n=NA follow-up: | - | first-line therapy of advanced breast cancer | |
| docetaxel vs doxorubicin + cyclophosphamide | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|---------------------------|
| JCOG , 2005 n=NA follow-up: | - | first-line chemotherapy in metastatic breast cancer | |
| docetaxel vs fluorouracil, vinorelbine | | | |
| TXT Group , 2002 n=NA follow-up: | docetaxel (100 mg m(-2)) every 3 weeks versus 5-fluorouracil+vinorelbine: 5-fluorouracil (750 mg m(-2) per day continuous infusion) D1-5 plus vinorelbine (25 mg m(-2)) D1 and D5 of each 3-week cycle | patients with metastatic breast cancer after failure of neo/adjuvant or one line of palliative anthracycline-based chemotherapy | |
| paclitaxel vs mitomycin | | | |
| Dieras , 1995 n=NA follow-up: | paclitaxel 175 mg/m2 given as a 3-hour infusion every 3 weeks versus mitomycin 12 mg/m2 given as an intravenous infusion every 6 weeks | advanced breast cancer | |
| docetaxel vs mitomycin, vinblastine | | | |
| 304 Study Group , 1999 n=203/189 follow-up: | docetaxel 100 mg/m2 intravenously (i.v.) every 3 weeks versus mitomycin 12 mg/m2 i.v. every 6 weeks plus vinblastine 6 mg/m2 i.v. every 3 weeks | patients with metastatic breast cancer progressing despite previous anthracycline-containing chemotherapy | open-label |
| docetaxel vs sequential methotrexate and 5-fluorouracil | | | |
| Sjostrom , 1999 n=143/139 follow-up: | Docetaxel at a dose of 100 mg/m2 every 3 weeks versus sequential methotrexate and 5-fluorouracil | patients with advanced breast cancer who had failed previous anthracycline treatment | |
| docetaxel vs vinorelbine | | | |
| Meier , 2008 n=NA follow-up: | weekly docetaxel (DOC), 6 weekly doses per 8-week cycle versus Weekly vinorelbine | after failing anthracycline treatment | |

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4 taxanes in combination

9

| Trial | Treatments | Patients | Trials design and methods |
|---|---|--|---------------------------|
| docetaxel + doxorubicin vs doxorubicin + cyclophosphamide | | | |
| 306 Study Group , 2003 n=214/215 follow-up: | doxorubicin 50 mg/m(2) plus docetaxel 75 mg/m(2) versus doxorubicin 60 mg/m(2) plus cyclophosphamide 600 mg/m(2) | first-line chemotherapy for metastatic breast cancer | |
| paclitaxel + doxorubicin vs doxorubicin + cyclophosphamide | | | |
| EORTC 10961 , 2002 n=NA follow-up: | Doxorubicin and paclitaxel versus doxorubicin and cyclophosphamide | first-line chemotherapy in metastatic breast cancer | |
| docetaxel + epirubicin vs epirubicin, cyclophosphamide | | | |
| Blohmer , 2010 n=NA follow-up: | ED (epirubicin 75 mg/m(2) and docetaxel 75 mg/m(2)) versus EC (epirubicin 90 mg/m(2) and cyclophosphamide 600 mg/m(2)). | first-line therapy for women with metastatic breast cancer | |
| paclitaxel + epirubicin vs epirubicin, cyclophosphamide | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|--|--|----------------------------------|
| UKCCCR AB01 , 1997 n=NA follow-up: | EP (epirubicin 75 mg/m2 and paclitaxel 200 mg/m2) versus EC (epirubicin 75 mg/m2 and cyclophosphamide 600 mg/m2) administered intravenously every 3 weeks for a maximum of six cycles | first-line chemotherapy for metastatic breast cancer | |
| docetaxel + doxorubicin vs fluorouracil, doxorubicin, cyclophosphamide | | | |
| Bontenbal , 2005 n=NA follow-up: | AT (doxorubicin 50 mg/m(2) and docetaxel 75 mg/m2) versus FAC (fluorouracil 500 mg/m2, doxorubicin 50 mg/m2, and cyclophosphamide 500 mg/m2); | first-line chemotherapy in patients with metastatic breast cancer: | |
| paclitaxel + doxorubicin vs fluorouracil, doxorubicin, cyclophosphamide | | | |
| Jassem , 2001 n=NA follow-up: | - | first-line therapy for women with metastatic breast cancer | |
| docetaxel + epirubicin vs fluorouracil, epirubicin, cyclophosphamide | | | |
| Bonneterre , 2004 n=NA follow-up: | docetaxel 75 mg m(-2) plus epirubicin 75 mg m(-2) versus 5-fluorouracil 500 mg m(-2) plus epirubicin 75 mg m(-2) and cyclophosphamide 500 mg m(-2) intravenously once every 3 weeks for up to eight cycles | - | |
| gemcitabine, epirubicin, paclitaxel vs fluorouracil, epirubicin, cyclophosphamide | | | |
| CECOG BM1 , 2005 n=NA follow-up: | gemcitabine (1,000 mg/m(2), days 1 and 4), epirubicin (90 mg/m(2), day 1), and paclitaxel (175 mg/m(2), day 1) versus FU (500 mg/m(2), day 1), epirubicin (90 mg/m(2), day 1), and cyclophosphamide (500 mg/m(2), day 1) | first-line chemotherapy in metastatic breast cancer | |
| docetaxel + trastuzumab vs vinorelbine, trastuzumab | | | |
| HERNATA , 2011 n=NA follow-up: | docetaxel 100 mg/m(2) day 1 versus vinorelbine 30 to 35 mg/m(2) on days 1 and 8 | first-line therapy of metastatic or locally advanced human epidermal growth factor receptor 2-positive breast cancer | |

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5 weekly taxanes

| Trial | Treatments | Patients | Trials design and methods |
|--|--|--|---------------------------|
| Weekly Docetaxel vs Every three weeks Docetaxel | | | |
| 65279;Rivera , 2008 n=NA follow-up: | Weekly Docetaxel 3540 mg/m2 versus Every three weeks Docetaxel 75100 mg/m2 | 65279;Metastatic patients with metastatic breast cancer | open |
| Taberbero , 2004 n=NA follow-up: | Weekly Docetaxel 40 mg/m2 versus Every three weeks Docetaxel 100 mg/m2 | Metastatic | |
| Sedky , 2002 n=NA | Weekly Docetaxel 35 mg/m2 versus Every three weeks Docetaxel 100 mg/m2 | Metastatic | |
| Willemse , 2007 n=NA | Weekly Docetaxel 36 mg/m2 versus Every three weeks Docetaxel 100 mg/m2 | Metastatic | |
| Weekly Paclitaxel vs Every three weeks Docetaxel | | | |
| Gradishar , 2009 n=NA follow-up: | Weekly Nab-paclitaxel 100 mg/m2 versus Every three weeks Docetaxel 100 mg/m2 | Metastatic | |
| Fountzilias , 2008 n=NA follow-up: | Weekly Paclitaxel 80 mg/m2 versus Every three weeks Gemc. Docetaxel 75 mg/m2 | Metastatic | |
| split dose vs Every three weeks Paclitaxel | | | |
| Khoo , 2006 n=NA follow-up: | split-dose paclitaxel or docetaxel in combination with gemcitabine versus Every three weeks Gemc. Paclitaxel 175 mg/m2 | Metastatic patients with metastatic breast cancer (MBC) who had previously received anthracyclines | |
| Weekly Paclitaxel vs Every three weeks Paclitaxel | | | |
| CLGB 9840 (Seidman) , 2008 n=NA follow-up: | Weekly Paclitaxel 80 mg/m2 versus Every three weeks Paclitaxel 175 mg/m2 | Metastatic | |
| Fraci , 2006 n=NA | Weekly Epi CDDP Paclitaxel 120 mg/m2 versus Every three weeks Epi Paclitaxel 175 mg/m2 | LABC | |
| Fraci , 2005 n=NA | Weekly Epi CDDP Paclitaxel 120 mg/m2 versus Every three weeks Epi Paclitaxel 175 mg/m2 | Metastatic | |
| Sikov , 2002 n=NA | Weekly Paclitaxel 150 mg/m2 versus Split D1,8 every three weeks Paclitaxel 175 mg/m2 | Metastatic | |

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65279;Rivera , 2008:

Rivera E, Mejia JA, Arun BK, Adinin RB, Walters RS, Brewster A, Broglio KR, Yin G, Esmaeli B, Hortobagyi GN, Valero V Phase 3 study comparing the use of docetaxel on an every-3-week versus weekly schedule in the treatment of metastatic breast cancer. *Cancer* 2008;112:1455-61 [[18300256](#)] [10.1002/cncr.23321](#)

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6 About TrialResults-center.org

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