Clinical trials of Capecitabine containing-regimen for advanced breast cancer (metastatic) in all type of patients

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1 capecitabine containing regimen

Trial	Treatments	Patients	Trials design and methods
capecitabine vs CMF			
Oshaughnessy , 2001 n=NA follow-up:	intermittent oral capecitabine 1,255 mg/m2 twice daily (two weeks' treatment followed by a one-week rest period) versus intravenous CMF (cyclophosphamide. methotrexate, 5-fluorouracil [5-FU]) administered every three weeks	-line therapy for advanced/metastatic breast cancer	
capecitabine vs control			
Joensuu , 2009 [NCT00114816] n=753/747 follow-up:	three cycles of capecitabine and docetaxel followed by three cycles of cyclophosphamide, epirubicin, and capecitabine versus three cycles of docetaxel followed by three cycles of cyclophosphamide, epirubicin, and fluorouracil	women with axillary node-positive or high-risk node-negative breast cancer	open-label
capecitabine vs cyclophosphamide, methotrexate, and 5-fluorouracil			
Stockler , 2011 n=NA	-	-	
capecitabine docetaxel vs docetaxel			
GeparQuattro , 2010 [NCT00288002] n=NA follow-up:	-	Patients with large operable or locally advanced tumors, with hormone receptor-negative tumors, or with receptor-positive tumors but also clinically node-positive disease	
capecitabine vs docetaxel + epirubicin			
Mavroudis , 2010 n=NA follow-up:	docetaxel 75 mg/m(2) on day 1 plus capecitabine 950 mg/m(2) orally twice daily on days 1-14 (DC) in 21-day cycles versus docetaxel 75 mg/m(2) plus epirubicin 75 mg/m(2) (DE) on day 1	women with advanced breast cancer	
capecitabine + docetaxel vs docetaxel alone			

continued...

Trial	Treatments	Patients	Trials design and methods
Verma , 2005 n=255/256 follow-up:	21-day cycles of oral capecitabine 1250 mg/m2 twice daily, on Days 1-14, plus docetaxel 75 mg/m2 Day 1 versus docetaxel 100 mg/m2 on Day 1	patients with anthracycline-pretreated metastatic breast carcinoma	
Miles , 2004 n=511 follow-up:	-	patients with anthracycline-pretreated advanced/metastatic breast cancer	
O'Shaughnessy , 2002 n=255/256 follow-up:	21-day cycles of oral capecitabine 1,250 mg/m(2) twice daily on days 1 to 14 plus docetaxel 75 mg/m(2) on day 1 versus docetaxel 100 mg/m(2) on day 1	patients with advanced breast cancer	
capecitabine + docetaxel vs doxorubicin + cyclophosphamide			
Lee , 2008 n=NA follow-up:	-	women with axillary node positive, stage II/III breast cancer	
capecitabine MPA vs IV CT			
Hori n=NA follow-up:	capecitabine, + medroxyprogesterone acetate (MPA) + cyclophosphamide versus 5-fluorouracil + adriamycin + CPA) plus MPA	metastatic breast cancer	
capecitabine vs paclitaxel			
Talbot , 2002 n=NA follow-up:	intermittent oral capecitabine (1255 mg m(-2) twice daily, days 1-14, (22 patients)) versus i.v. paclitaxel (175 mg m(-2),	patients with metastatic/advanced breast cancer pretreated with anthracyclines	
Moiseenko , 2000 n=NA follow-up:	-	-	
capecitabine vs pegylated liposomal doxorubicin			
Jger , 2010 n=NA	-	-	
capecitabine vs vinorelbine			
EORTC 10001 (Pajk) , 2008 n=NA follow-up:	capecitabine 1250 mg/m(2) orally bid days 1-14 versus vinorelbine 30 mg/m(2) i.v. days 1 and 8, both given every 3 weeks	patients with anthracycline- and taxane-pretreated metastatic breast cancer	

References

Oshaughnessy, 2001:

Oshaughnessy JA, Blum J, Moiseyenko V, Jones SE, Miles D, Bell D, Rosso R, Mauriac L, Osterwalder B, Burger HU, Laws S, Randomized, open-label, phase II trial of oral capecitabine (Xeloda) vs. a reference arm of intravenous CMF (cyclophosphamide, methotrexate and 5-fluorouracil) as first-line therapy for advanced/metastatic breast cancer. Ann

Oncol 2001;12:1247-54. [11697835]

Joensuu, 2009:

Joensuu H, Kellokumpu-Lehtinen PL, Huovinen R, Jukkola-Vuorinen A, Tanner M, Asola R, Kokko R, Ahlgren J, Auvinen P, Hemminki A, Paija O, Helle L, Nuortio L, Villman K, Nilsson G, Lahtela SL, Lehti K, Pajunen M, Poikonen P, Nyandoto P, Kataja V, Bono P, Adjuvant capecitabine in combination with docetaxel and cyclophosphamide plus epirubicin for breast cancer: an open-label, randomised controlled trial. Lancet Oncol 2009;10:1145-51. [19906561] 10.1016/S1470-2045(09)70307-9

Joensuu H, Kellokumpu-Lehtinen PL, Huovinen R, Jukkola-Vuorinen A, Tanner M, Kokko R, Ahlgren J, Auvinen P, Lahdenper O, Kosonen S, Villman K, Nyando Adjuvant Capecitabine in Combination With Docetaxel, Epirubicin, and Cyclophosphamide for Early Breast Cancer: The Randomized Clinical FinXX Trial. JAMA Oncol 2017;: [28253390]

Stockler, 2011:

Stockler MR, Harvey VJ, Francis PA, Byrne MJ, Ackland SP, Fitzharris B, Van Hazel G, Wilcken NR, Grimison PS, Nowak AK, Gainford MC, Fong A, Paksec L, Sourjina T, Zannino D, Gebski V, Simes RJ, Forbes JF, Coates AS Capecitabine versus classical cyclophosphamide, methotrexate, and fluorouracil as first-line chemotherapy for advanced breast cancer. J Clin Oncol 2011;29:4498-504 [22025143] 10.1200/JCO.2010.33.9101

GeparQuattro, 2010:

von Minckwitz G, Rezai M, Loibl S, Fasching PA, Huober J, Tesch H, Bauerfeind I, Hilfrich J, Eidtmann H, Gerber B, Hanusch C, Khn T, du Bois A, Blohmer JU, Thomssen C, Dan Costa S, Jackisch C, Kaufmann M, Mehta K, Untch M, Capecitabine in addition to anthracycline- and taxane-based neoadjuvant treatment in patients with primary breast cancer: phase III GeparQuattro study. J Clin Oncol 2010;28:2015-23. [20308671] 10.1200/JCO.2009.23.8303

Mavroudis, 2010:

Mavroudis D, Papakotoulas P, Ardavanis A, Syrigos K, Kakolyris S, Ziras N, Kouroussis C, Malamos N, Polyzos A, Christophyllakis C, Kentepozidis N, Georgoulias V, , Randomized phase III trial comparing docetaxel plus epirubicin versus docetaxel plus capecitabine as first-line treatment in women with advanced breast cancer. Ann Oncol 2010;21:48-54. [19906761] 10.1093/annonc/mdp498

Verma, 2005:

Verma S, Maraninchi D, O'Shaughnessy J, Jamieson C, Jones S, Martn M, McKendrick J, Miles D, Twelves C, Hornberger J, Capecitabine plus docetaxel combination therapy. Cancer 2005;103:2455-65. [15892043] 10.1002/cncr.21122

Miles, 2004:

Miles D, Vukelja S, Moiseyenko V, Cervantes G, Mauriac L, Van Hazel G, Liu WY, Ayoub JP, O'Shaughnessy JA, Survival benefit with capecitabine/docetaxel versus docetaxel alone: analysis of therapy in a randomized phase III trial. Clin Breast Cancer 2004;5:273-8. [15507172]

O'Shaughnessy, 2002:

O'Shaughnessy J, Miles D, Vukelja S, Moiseyenko V, Ayoub JP, Cervantes G, Fumoleau P, Jones S, Lui WY, Mauriac L, Twelves C, Van Hazel G, Verma S, Leonard R, Superior survival with capecitabine plus docetaxel combination therapy in anthracycline-pretreated patients with advanced breast cancer: phase III trial results. J Clin Oncol 2002;20:2812-23. [12065558]

Lee, 2008:

Lee KS, Ro J, Nam BH, Lee ES, Kwon Y, Kwon HS, Chung KW, Kang HS, Kim EA, Kim SW, Shin KH, Kim SK, A randomized phase-III trial of docetaxel/capecitabine versus doxorubicin/cyclophosphamide as primary chemotherapy for patients with stage II/III breast cancer. Breast Cancer Res Treat 2008;109:481-9. [17653851] 10.1007/s10549-007-9672-y

Hori, 0:

Hori T, Kodama H, Nishimura S, Hatano T, Okamura R, Fujii K, Kudo T, Inamoto T, Sawai K, Kobayashi M, Ogawa H, Yoshimura N, Hiraoka M, A randomized study comparing oral and standard regimens for metastatic breast cancer. Oncol Rep ;8:1067-71. [11496318]

Talbot, 2002:

Talbot DC, Moiseyenko V, Van Belle S, O'Reilly SM, Alba Conejo E, Ackland S, Eisenberg P, Melnychuk D, Pienkowski T, Burger HU, Laws S, Osterwalder B, Randomised, phase II trial comparing oral capecitabine (Xeloda) with paclitaxel in patients with metastatic/advanced breast cancer pretreated with anthracyclines. Br J Cancer 2002;86:1367-72. [11986765] 10.1038/sj.bjc.6600261

Moiseenko, 2000:

Moiseenko VM, O'Reilly SM, Dalbot DC, Van Belle S, Gordon RJ, Griffin T, Osterwalder B, [A comparative randomized phase-II study of Xeloda (capecitabine) and paclitaxel in patients with breast cancer progressing after anthracycline antibiotics] Vopr Onkol 2000;46:285-9. [10976273]

Jger, 2010:

Jger E, Al-Batran S, Saupe S et al. A randomized phase III study evaluating pegylated liposomal doxorubicin (PLD) versus capecitabine (CAP) as first-line therapy for metastatic breast cancer (MBC): Results of the PELICAN study J Clin Oncol 2010;28(15 suppl):1022.

EORTC 10001 (Pajk), 2008:

Pajk B, Cufer T, Canney P, Ellis P, Cameron D, Blot E, Vermorken J, Coleman R, Marreaud S, Bogaerts J, Basaran G, Piccart M, Anti-tumor activity of capecitabine and vinorelbine in patients with anthracycline- and taxane-pretreated metastatic breast cancer: findings from the EORTC 10001 randomized phase II trial. Breast 2008;17:180-5. [17976988] 10.1016/j.breast.2007.09.002

2 About TrialResults-center.org

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