

Clinical trials of monoclonal antibody for early breast cancer in primary operable breast cancer

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Trial	Treatments	Patients	Trials design and methods
trastuzumab during chemotherapy vs control			
NSABP B-31 n=864/872 follow-up: 2.9 years	same regimen plus 52 weeks of trastuzumab beginning with the first dose of paclitaxel versus doxorubicin and cyclophosphamide followed by paclitaxel every 3 weeks	Early-stage, node-positive invasive breast cancer	

References

NSABP B-31, :

Romond EH, Perez EA, Bryant J, Suman VJ, Geyer CE Jr, Davidson NE, Tan-Chiu E, Martino S, Paik S, Kaufman PA, Swain SM, Pisansky TM, Fehrenbacher L, Kutteh LA, Vogel VG, Visscher DW, Yothers G, Jenkins RB, Brown AM, Dakhil SR, Mamounas EP, Lingle WL, Klei Trastuzumab plus adjuvant chemotherapy for operable HER2-positive breast cancer. *N Engl J Med* 2005;353:1673-84 [[16236738](#)] [10.1056/NEJMoa052122](#)

2 after chemotherapy

Trial	Treatments	Patients	Trials design and methods
trastuzumab vs			
HERA (BIG 01-01) 2-years , 2005 [NCT00045032] n=NA follow-up: 2 years	two years of trastuzumab given every three weeks versus observation	patients with HER2-positive and either node-negative or node-positive breast cancer who had completed locoregional therapy and at least four cycles of neoadjuvant or adjuvant chemotherapy	Parallel groups open
trastuzumab vs control			
HERA (BIG 01-01) 1-year , 2005 [NCT00045032] n=1694/1693 follow-up: 2 years	one years of trastuzumab given every three weeks versus observation	patients with HER2-positive and either node-negative or node-positive breast cancer who had completed locoregional therapy and at least four cycles of neoadjuvant or adjuvant chemotherapy	Parallel groups open

continued...

Trial	Treatments	Patients	Trials design and methods
NCCTG N9831(C vs A) n=808/807 follow-up: 2.9 years	same regimen plus 52 weeks of trastuzumab initiated concomitantly with paclitaxel versus doxorubicin and cyclophosphamide followed by weekly paclitaxel	Early-stage invasive breast cancer, node positive or high-risk node negative (tumor 1 cm if HR negative or 2 cm if HR positive)	

References

HERA (BIG 01-01) 2-years, 2005:

Smith I, Procter M, Gelber RD, Guillaume S, Feyereislova A, Dowsett M, Goldhirsch A, Untch M, Mariani G, Baselga J, Kaufmann M, Cameron D, Bell R, Bergh J, Coleman R, Wardley A, Harbeck N, Lopez RI, Mallmann P, Gelmon K, Wilcken N, Wist E, Snchez Rovira 2-year follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer: a randomised controlled trial. *Lancet* 2007;369:29-36 [17208639] [10.1016/S0140-6736\(07\)60028-2](https://doi.org/10.1016/S0140-6736(07)60028-2)

Cameron D, Piccart-Gebhart MJ, Gelber RD, Procter M, Goldhirsch A, de Azambuja E, Castro G Jr, Untch M, Smith I, Gianni L, Baselga J, Al-Sakaff N, Lau 11 years' follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive early breast cancer: final analysis of the HERceptin Adjuvant (HERA) trial. *Lancet* 2017;: [28215665]

Cameron D, Piccart-Gebhart MJ, Gelber RD, Procter M, Goldhirsch A, de Azambuja E, Castro G Jr, Untch M, Smith I, Gianni L, Baselga J, Al-Sakaff N, Lau 11 years' follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive early breast cancer: final analysis of the HERceptin Adjuvant (HERA) trial. *Lancet* 2017;: [28215665]

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Piccart-Gebhart MJ, Procter M, Leyland-Jones B, Goldhirsch A, Untch M, Smith I, Gianni L, Baselga J, Bell R, Jackisch C, Cameron D, Dowsett M, Barrios CH, Steger G, Huang CS, Andersson M, Inbar M, Lichinitser M, Lng I, Nitz U, Iwata H, Thomssen C, Lohris Trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer. *N Engl J Med* 2005;353:1659-72 [16236737] [10.1056/NEJMoa052306](https://doi.org/10.1056/NEJMoa052306)

NCCTG N9831(C vs A), :

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3 during chemotherapy

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