

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

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## 1 aaa

| Trial   | Treatments   | Patients  | Trials design and methods |
|---|--|---|---------------------------|
| <b>trastuzumab during chemotherapy vs control</b> |  |   |                           |
| NSABP B-31<br>n=864/872<br>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 |
|--|---|---|---------------------------|
| <b>trastuzumab vs</b>  |   |   |                           |
| HERA (BIG 01-01) 2-years , 2005<br>[NCT00045032]<br>n=NA<br>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<br>open   |
| <b>trastuzumab vs control</b>  |   |   |                           |
| HERA (BIG 01-01) 1-year , 2005<br>[NCT00045032]<br>n=1694/1693<br>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<br>open   |

continued...

| Trial  | Treatments  | Patients  | Trials design and methods |
|--|---|---|---------------------------|
| NCCTG N9831(C vs A)<br>n=808/807<br>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]

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## 3 during chemotherapy

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| <b>trastuzumab vs control</b>  |   |   |                           |
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3

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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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