BREAST

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Country: Europe, Africa, South America, Middle East

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Title: An intergroup phase III trial to evaluate the activity of docetaxel, given either sequentially or in combination with doxorubicin, followed by CMF, in comparison to doxorubicin alone or in combination with cyclophosphamide, followed by CMF, in the adjuvant treatment of node-positive breast cancer patients.
BIG 02-98/TAX 315

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Summary:

- Opened in June 1998
- Target accrual: 2730 patients

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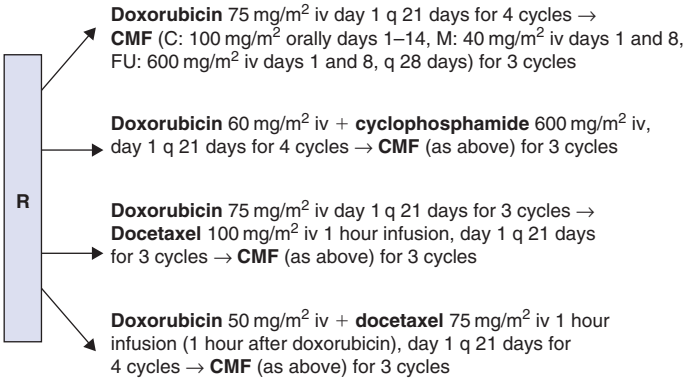
Primary Objectives:

- To compare disease-free survival of an adjuvant treatment with doxorubicin followed by docetaxel, followed by CMF to doxorubicin followed by CMF in operable breast cancer patients with positive axillary lymph nodes.
- To compare disease-free survival of an adjuvant treatment with docetaxel in combination with doxorubicin followed by CMF to doxorubicin in combination with cyclophosphamide followed by CMF in operable breast cancer patients with positive axillary lymph nodes.

Secondary Objectives:

- To compare disease-free survival of an adjuvant treatment with docetaxel given either sequentially or in combination with doxorubicin and followed by CMF to doxorubicin alone or in combination with cyclophosphamide and followed by CMF in operable breast cancer patients with positive axillary lymph nodes.
- To compare disease-free survival of an adjuvant treatment with doxorubicin followed by docetaxel, followed by CMF to doxorubicin in combination with docetaxel followed by CMF in operable breast cancer patients with positive axillary lymph nodes (sequential monochemotherapy *versus* polychemotherapy).
- To compare overall survival of treatment arms.
- To compare toxicity of treatment arms.
- To evaluate pathologic and molecular markers for predicting efficacy.
- Socioeconomic data will be collected in order to be able to perform a socioeconomic analysis by country, when needed.

Scheme:



Tamoxifen 20 mg/day for 5 years if ER and/or PgR positive

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Radiotherapy:

Radiotherapy mandatory in case of breast-conservative surgery; allowed in case of mastectomy, according to the policy in use at each participating center.

Update:

- Trial closed 26 June 2001.
- Total patients randomized: 2890.

Related Publications: None available

Topics:

- Taxanes
- Node-positive breast cancer
- Anthracyclines

Keywords: None available

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Title: HERA: A randomized three-arm multi-centre comparison of 1 year and 2 years of Herceptin *versus* no Herceptin in women with HER2-positive primary breast cancer who have completed adjuvant chemotherapy.
BIG 01-01/B016348

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Summary: *Primary Objectives:*

- To compare disease-free survival (DFS) in patients with HER2 overexpressing breast cancer who have been randomized to Herceptin for 1 year *versus* no Herceptin.
- To compare DFS in patients with HER2 overexpressing breast cancer who have been randomized to Herceptin for 2 years *versus* no Herceptin.

Secondary Objectives:

- To compare overall survival (OS) in patients randomized to: (i) Herceptin for 1 year or no further therapy and (ii) Herceptin for 2 years or no further therapy.
- To compare relapse-free survival (RFS).
- To compare distant disease-free survival (DDFS).
- To evaluate the safety and tolerability of Herceptin.
- To compare the incidence of cardiac dysfunction in patients treated and not treated with Herceptin.
- To compare outcomes (DFS, OS, RFS, DDFS, cardiac safety, overall safety) of patients treated with Herceptin for 1 year compared with Herceptin for 2 years.

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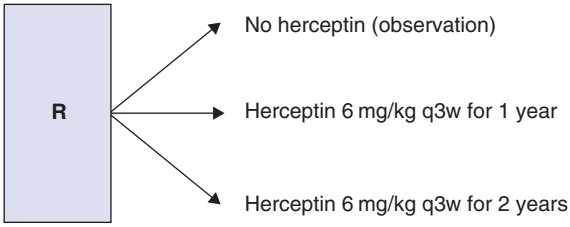
Scheme:

Primary management pre-HERA
(Surgery, [neo-]adjuvant chemotherapy + adjuvant radiotherapy)



Update:

- Trial closed 20 June 2005.
- Total number of patients randomized is 5102

Related Publications:

Martine J. Piccart-Gebhart *et al.* Trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer. *New Eng J Med* 2005; 353: 1659–1672.

Topics:

- HER2 positive patients
- Hormone receptor negative breast cancer
- Hormone receptor positive breast cancer
- Node negative breast cancer
- Node positive breast cancer
- Trastuzumab

Keywords:

None available

https://doi.org/10.1017/S1470903106009072 Published online by Cambridge University Press

Title: BIG2-06 / N063D: Phase III Trial of Trastuzumab and/or Lapatinib in Patients with HER2+ Breast Cancer (Full title/acronym not available at time of publication).

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Summary:

Primary Objectives:

- To compare disease-free survival (DFS) in patients with HER2 overexpressing and/or amplified breast cancer randomized to trastuzumab for 1 year *versus* lapatinib for 1 year *versus* a sequence of trastuzumab and lapatinib (1 year total) versus a combination of trastuzumab and lapatinib (1 year total).

Secondary Objectives:

- To compare overall survival (OS) in patients randomized to the four arms.
- To compare time to recurrence (TTR).
- To compare time to distant recurrence (TTDR).
- To evaluate the safety and tolerability of all four treatment groups.
- To compare the cumulative incidence of brain metastases as the first site of breast cancer recurrence.

Target accrual: $n = 8000$

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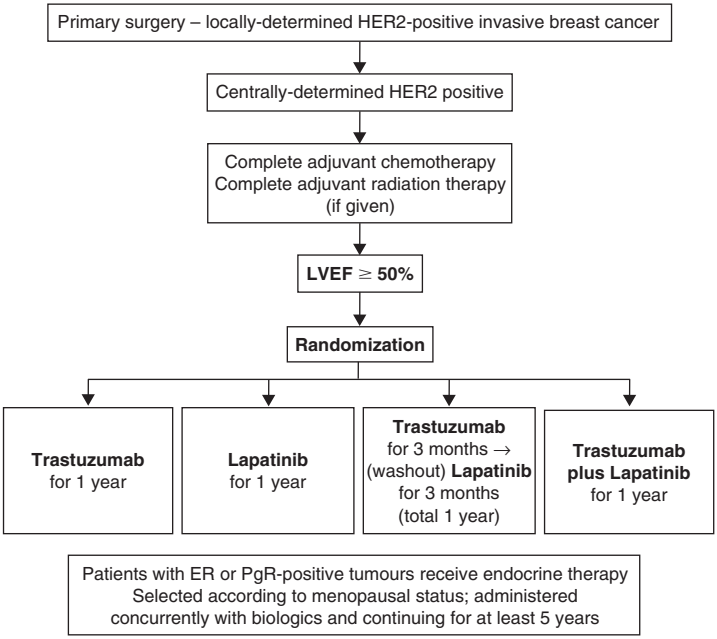
Scheme:



Update:

- Trial will open for accrual beginning of 2007.

Related Publications:

None available

Topics:

- HER2 positive patients
- Hormone receptor negative breast cancer
- Hormone receptor positive breast cancer
- Node negative breast cancer
- Node positive breast cancer
- Trastuzumab

Keywords:

Phase III, adjuvant breast cancer, HER2+, trastuzumab, lapatinib, herceptin, tykerb

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Title: Phase III Neo-adjuvant trial of lapatinib, trastuzumab and their combination plus paclitaxel in women with HER2/ErbB2 positive primary breast cancer (exact title/ acronym not available at time of publication)
BIG 1-06

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Summary: *Primary Objectives:*

- To evaluate and compare the rate of pCR at the time of surgery in patients with HER2/ErbB2 overexpressing or amplified operable breast cancer randomized to lapatinib followed by lapatinib plus paclitaxel versus tratsuzumab followed by trastuzumab and paclitaxel versus lapatinib in combination with trastuzumab followed by lapatinib, trastuzumab and paclitaxel

Secondary Objectives:

- To compare the safety and tolerability of the three treatment arms;
- To compare the objective response rate (complete plus partial responses) among the three treatment arms;
- To compare the percent of patients with node-negative disease at surgery among the three treatment arms;
- To compare the rate of conversion to breast conserving surgery among the three treatment arms;
- To compare disease free (DFS) and overall survival (OS);
- To identify the molecular characteristics of responding tumors by immunohistochemical, FISH, genomic and proteomic analysis;
- To study biomarkers expression before and during therapy and establish correlations with clinical outcome;
- To establish associations between PET/CT and tumor response.

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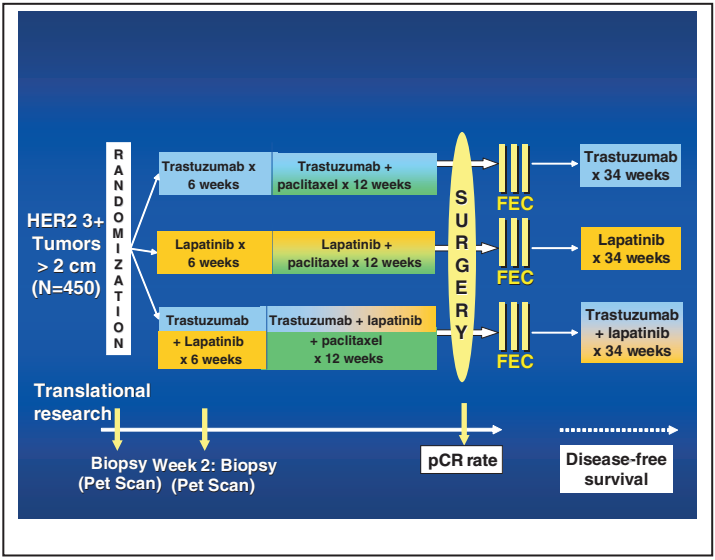
Scheme:



Update:

- *n* = 450; trial will open for accrual at the beginning of 2007.

Related Publications: None available

Topics:

- HER2 positive patients, trastuzumab

Keywords: Phase III, neo-adjuvant, HER2+, trastuzumab, lapatinib, herceptin, tykerb, paclitaxel

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