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Title: WSG and AGO-Mamma Intergroup Study: Randomized phase III trial of EC⟶Doc: adjuvant chemotherapy of breast carcinoma with 1–3 positive lymph nodes. EC-DOC (AM02)

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Summary:

- Opened in September 2000, closed in August 2005
- Target accrual: 2000

Objectives:

- Event free survival (EFS) and overall survival (OS)
- Comparison of:
  (a) Toxicity
  (b) Quality of Life (QOL)
  (c) Cost effectiveness analysis

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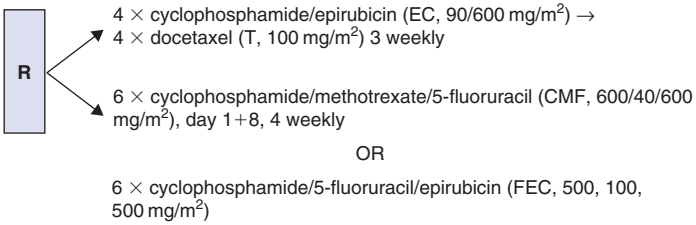
Scheme:



Update:

- Randomisation closed; 2011 patients randomised.

Related Publications:

Huober J, Thomssen C, Fischer H, *et al*. First toxicity analysis of a randomized adjuvant German Intergroup Phase 3-Study for patients with primary breast cancer (bc) with 1–3 involved lymph nodes comparing six cycles FEC or CMF to four cycles of EC followed by 4 cycles of Docetaxel (Doc). *EBCC*, Hamburg 2004

Samuelkutty S, Gluz O, Mohrmann S, *et al*. Chemotherapy-induced amenorrhea (CIA) in patients treated with adjuvant CEF/CMF or EC/docetaxel: analysis from a phase III randomized EC/Doc Trial. SABCS 2005: *Breast Cancer Res Treat* 2005; 94(Suppl 1) *2063

Schütt G, Mohrmann S, Kuhn W, *et al*. Age-associated incindence of chemotherapy-related amenorrhea (CRA) and results of the second toxicity analysis of a WSG/AGO-Mamma Intergroup Phase III trial AM02 "EC→Doc" for patients with primary breast cancer and 1–3 positive axillary lymph nodes. *St Gallen Consensus Conference* 2005.

Topics:

- Taxanes
- Node positive breast cancer

Keywords: Breast cancer, chemotherapy, 1–3 involved lymph nodes, taxanes

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Title: WSG Study: Randomized phase III trial of adjuvant CEF/TAC chemotherapy +/− Darbepoetin alfa for patients with primary breast cancer and more than 3 positive axillary lymph nodes. ARA Plus (AM03)

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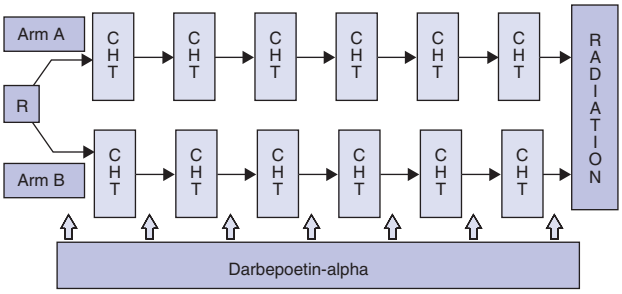
Summary:

- Target accrual: 1234

Objectives:

- Event-free survival (EFS).
- Overall Survival (OS).
- Comparison of toxicity, anaemia and cognitive function.
- Comparison of fatigue syndrome.

Scheme:



CHT: TAC: 6 × docetaxel 75 mg/m^2 + doxorubicin 50 mg/m^2 + cyclophosphamide 500 mg/m^2 q3w or CEF: 6 × cyclophosphamide 500 mg/m^2 + epirubicin 100 mg/m^2 + 5-FU 500 mg/m^2 q3w

R = randomization

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Update:	• 650 patients randomized at end September 2006.
Related Publications:	None available
Topics:	• Node positive breast cancer
Keywords:	Erythropoetin

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Title: ICE – Study: Ibandronate with or without capecitabine in elderly patients with early breast cancer. BIG 4-04 / GBG 32. (see also description under GBG)

Coordinator(s):

An Intergroup Study of the:
Westdeutsche Studiengruppe (WSG)
Arbeitsgemeinschaft Gynäkologische Onkologie (AGO)
German Breast Group (GBG)
Nordostdeutsche Gesellschaft für Gynäkologische Onkologie (NOGGO)

Protocol Board:

Professor Dr U. Nitz, Düsseldorf (Principal investigator; WSG)
PD Dr D. Elling, Berlin (NOGGO)
Professor Dr V. Möbus Frankfurt (AGO)
PD Dr G. von Minckwitz Frankfurt (GBG)

Summary:

Primary Objective:

- To compare the event-free survival in elderly patients after local treatment for primary breast cancer treated with either ibandronate alone or ibandronate and capecitabine as adjuvant treatment.

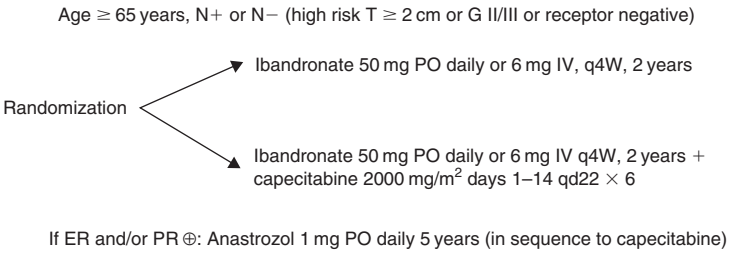
Secondary Objectives:

- To compare the overall survival between the two Arms.
- To determine the compliance in both Arms.
- To determine the toxicity in both Arms.
- To determine the rate of bone-related events in hormonsensitive and insensitive disease (with or without anastrozol).
- To determine the preference to oral or intravenous application of ibandronate.
- To assess quality of life.

Tertiary Objective:

- To determine prognostic factors on tumor tissue collected from primary surgery and to correlate them with study treatment effect.

Scheme:



Update:

- Planned accrual: 1394 patients.

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Related Publications: None available

Topics:
- Bisphosphonates
- Capecitabine
- Elderly patients
- Hormonal therapy
- Predictive markers

Keywords: None available

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