ACCOG

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Country: United Kingdom

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Title: Intensive chemotherapy for high-risk (>4 axillary lymph nodes) breast cancer.

Study Anglo Celtic I

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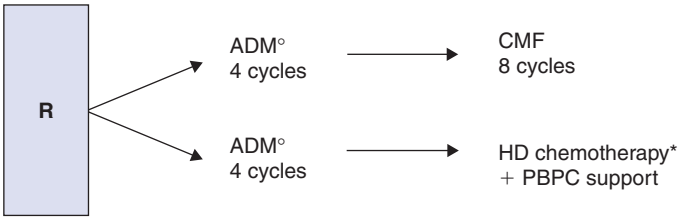
Summary:

- Closed in June 1999 (opened in February 1995)
- Target accrual: 600 patients

Objective:

- To determine the comparative efficacy of a high-dose sequential chemotherapy programme *versus* conventional CMF following doxorubicin induction in patients with high-risk primary breast cancer.

Scheme:



° ADM (doxorubicin) 75 mg/m^{2}every 21 days

* cyclophosphamide 6.0 g/m^2 + thiotepa 800 mg/m^2

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Update:

- Study closed in June 1999.
- 605 patients entered.
- Early results were presented by poster at ASCO 2002.

Related Publications:

Conventional adjuvant chemotherapy *versus* single-cycle, autograft-supported, high-dose, late-intensification chemotherapy in high-risk breast cancer patients: a randomized trial. *J Nat Cancer Inst* 2004; 96(14): 1076–1083.

Topics:

- High-dose chemotherapy
- Node positive breast cancer

Keywords:

Breast cancer, high-dose chemotherapy

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Title: A randomised comparative trial of Adriamycin and Taxotere versus Adriamycin and Cyclophosphamide as primary therapy for patients with potentially operable disease >3cm diameter, locally advanced or inflammatory breast cancer.

Study Anglo Celtic II

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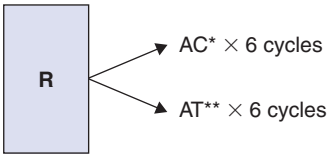
Summary:

- Opened in October 1998
- Target accrual: 350 patients

Objective:

- To compare the efficacy (response rates) and toxicity of Adriamycin and Taxotere *versus* Adriamycin and Cyclophosphamide as primary medical therapy regimens in early breast cancer.

Scheme:



*AC = Adriamycin 60 mg/m^2 plus
Cyclophosphamide 600 mg/m^2, i.v. q 3 weeks

**AT = Adriamycin 50 mg/m^2 plus
Taxotere 75 mg/m^2, i.v. q 3 weeks

Update:

- Study closed 2001.

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- 363 patients entered.
- Early results were presented by poster at ASCO 2002.

Related Publications: Evans TR, Yellowlees A, Foster E *et al.* Phase III randomized trial of doxorubicin and docetaxel *versus* doxorubicin and cyclophosphamide as primary medical therapy in women with breast cancer: an anglo-celtic cooperative oncology group study. *J Clin Oncol* 2005; 23(13): 2988–2995.

Topics:
- Taxanes
- Anthracyclines

Keywords: Primary medical therapy, breast cancer

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Title: Prospective randomized comparison of G-CSF (filgrastim) secondary prophylaxis *versus* conservative management of chemotherapy-induced neutropenia to maintain dose intensity in chemotherapy for breast cancer.

Study Anglo Celtic III

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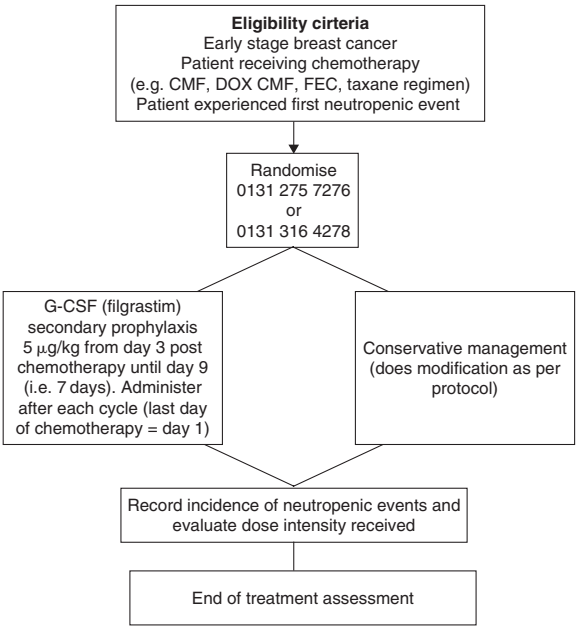
Summary:

- Opened in October 2001
- Target accrual: 400 patients

Objective:

- To compare the effects of G-CSF secondary prophylaxis against standard management after the first neutropenic event in achieving planned dose intensity of chemotherapy for early breast cancer.

Scheme:



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Update:	• Recruitment target reduced to 400; 367 patients recruited to date.
Related Publications:	None available
Topics:	• GCSF secondary prophylaxis
Keywords:	Early breast cancer, dose intensity

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Title: A randomized 2-arm, prospective, multi-centre, open label phase III trial comparing the activity and safety of a weekly *versus* a 3-weekly paclitaxel treatment schedule in patients with advanced or metastatic breast cancer.

Study Anglo Celtic IV
"Will Weekly Win", www.taxol-uk.com

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Summary:

- Opened in September 2002
- Target accrual: 600 patients

Primary Objectives:

- To compare the antitumour efficacy of weekly *versus* 3-weekly paclitaxel as determined by the time to disease progression.
- To study polymorphisms in the genes responsible for paclitaxel metabolism and link these to response rates and toxicity.

Secondary Objectives:

- To compare the toxicity of weekly *versus* 3-weekly paclitaxel.
- To compare the response rate of weekly *versus* 3-weekly paclitaxel.
- To compare overall survival in patients receiving weekly *versus* 3-weekly paclitaxel.
- To compare quality of life in patients receiving weekly *versus* 3-weekly paclitaxel.

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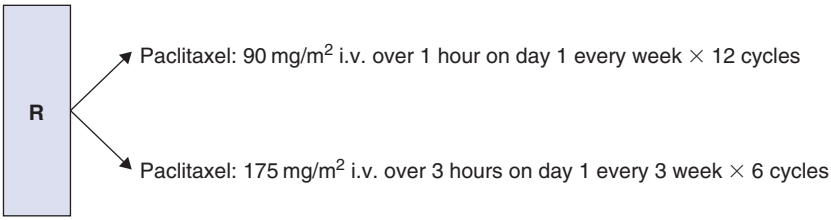
Scheme:



Update:

- 569 patients have been randomized from 55 active centres.
- Early results willl be presented at NCRI 2006.

Related Publications: None available

Topics:

- Metastatic breast cancer
- Taxanes

Keywords: Chemotherapy scheduling

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Title: Ovarian protection trial in oestrogen non-responsive premenopausal breast cancer patients receiving adjuvant or neo-adjuvant chemotherapy.

Anglo Celtic V – OPTION

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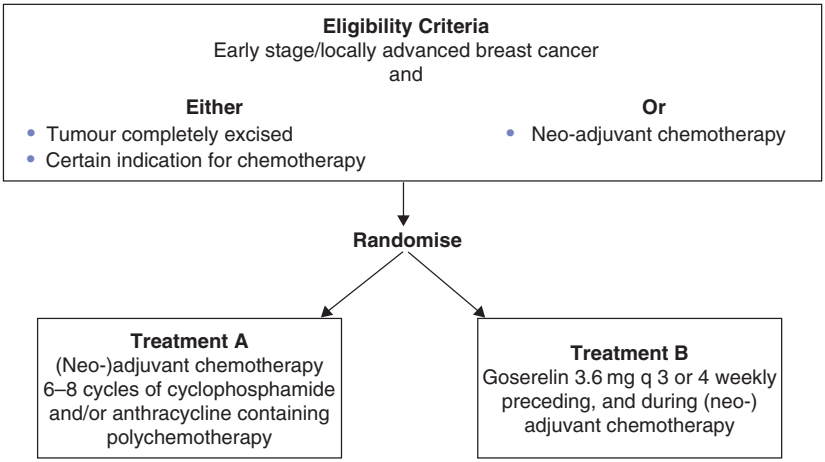
Summary:

- A study to assess the value of goserelin ovarian suppression in the prevention of chemotherapy-associated menopause in premenopausal women with early or locally advanced breast cancer.

Scheme:

Study Schema



Update:

- Over 70 centres in the UK open for recruitment; 67 patients recruited to date.

Related Publications: None available

Topics:

- Premenopausal patients
- Fertility and chemotherapy

Keywords: Early breast cancer, ovarian protection

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