WMBG

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Country: United Kingdom

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Title: aTTom – adjuvant Tamoxifen Treatment – offer more?

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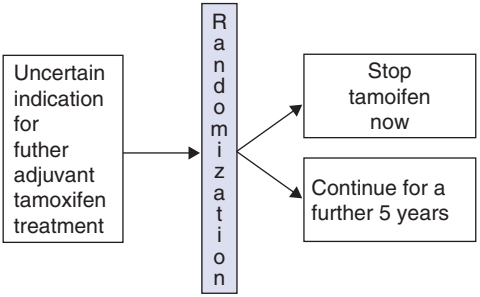
Summary: *Objective:*

- A large, uniquely simple, randomized study to assess much more reliably the balance of benefits and risks of prolonging adjuvant tamoxifen treatment in early breast cancer. Eligibility criteria are pragmatic, with randomization taking place at the point when *substantial uncertainty* arises as to whether to stop or to continue tamoxifen.

Target Accrual:

- 8000 patients from the UK and Republic of Ireland; 20,000 patients worldwide, in collaboration with its global counterpart ATLAS (Adjuvant Tamoxifen – Longer Against Shorter), which is coordinated by the Clinical Trial Service Unit at the University of Oxford, UK.

Scheme:



Update:

- In January 2005, the aTTom Trial Steering Committee (TSC), in consultation with the ATLAS TSC, made the decision that recruitment to aTTom should close as over 20,000 women in total had been randomized when the two studies and a few smaller studies were considered. It was anticipated that closure to recruitment would allow the trial team and the study collaborators to concentrate on continuing to encourage compliance with the randomized treatment allocation and ensure complete follow-up of women already enrolled

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in the trial. The aTTom trial closed to recruitment on 31/03/2005 with a cumulative total of 8861 patients randomized.

Related Publications: None available

Topics:
- Tamoxifen
- Tamoxifen duration
- Hormonal therapy

Keywords: Breast cancer, hormone therapy, antioestrogen, tamoxifen

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Title: Sequencing of chemotherapy and radiotherapy in adjuvant breast cancer. **SECRAB**

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Summary:

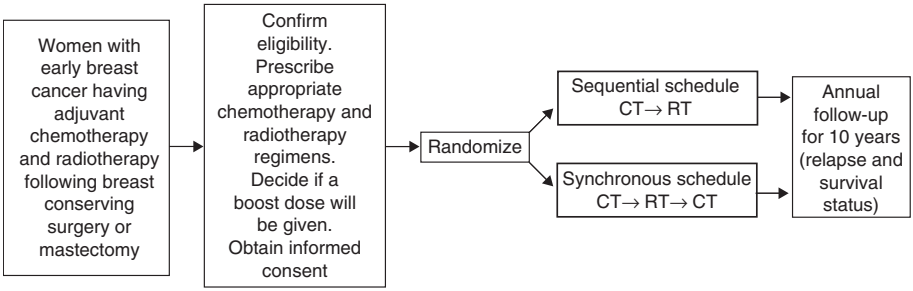
Objective:

- To determine if local control can be improved by the synchronous delivery of adjuvant chemotherapy and radiotherapy, thereby not delaying the administration of either modality; and to determine if the two treatment modalities can be given together safely.

Target Accrual:

- 2250 patients.

Scheme:



Update:

- The study opened for recruitment in July 1998 and closed on 25 March 2004 having surpassed its recruitment target by 48 patients. Forty-seven consultants form 63 centres from the UK participated in the study. The *SECRAB* trial is to the best of our knowledge the largest trial addressing the question of the optimal sequence of chemotherapy and radiotherapy in the world to date. It is adequately powered to detect a difference of 4% in 5-year actuarial loco-regional relapse rates. The eagerly awaited results will provide valuable

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evidence in determining whether delaying radiotherapy to complete chemotherapy is detrimental and whether combined chemo-radiotherapy offers a means of maintaining local control without excess toxicity.

Related Publications: Bowden SJ, Fernando IN, Burton A. Delaying radiotherapy for the delivery of adjuvant chemotherapy in the combined modality treatment of early breast cancer: is it disadvantageous and could combined treatment be the answer? *Clin Oncol* 2006; 18: 247–256.

Topics:

- Radiotherapy
- Loco-regional relapse

Keywords: Breast cancer, chemotherapy, radiotherapy, chemo-radiotherapy, sequencing, toxicity

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Title: A phase III randomized trial of gemcitabine in paclitaxel-containing, epirubicin-based, adjuvant chemotherapy for women with early stage breast cancer.
tAnGo

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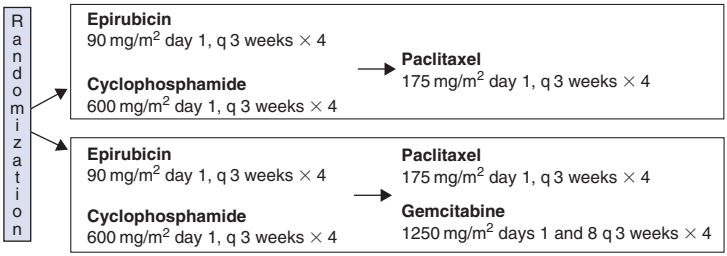
Summary: *Objective:*

- To determine whether the addition of gemcitabine to the second phase of a control regimen of epirubicin and cyclophosphamide followed by paclitaxel improves disease-free survival in relation to epirubicin and cyclophosphamide followed by paclitaxel alone, in women presenting with early stage breast cancer.

Target Accrual:

- 3000 patients.

Scheme:



Update:

- Recruitment commenced in November 2001 with a preliminary safety study, which was mandatory for the first 130 patients enrolled. This involved detailed monitoring of patients' cardiac and pulmonary function. Accrual of this sub-study was completed in October 2002 and the main trial was officially launched in January 2003. Following this, with an average monthly recruitment of 130 patients an early closure was announced for 26 November 2004, which saw the trial accruing a total 3152 patients from 127 centres from the UK and

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Republic of Ireland (RoI). All patients completed treatment by June 2005 and are now in follow-up.

Related Publications

Poole CJ *et al.* A prospective evaluation of pulmonary, cardiac, and hepatic function (fn) in "*tAnGo*": a randomized phase III trial of gemcitabine (G) in paclitaxel (T)-containing, epirubicin/cyclophosphamide (EC)-based, adjuvant chemotherapy (CT) for early stage breast. ASCO Meeting Abstract 821, 2004.

Poole CJ *et al*. Tolerability of gemcitabine in paclitaxel-containing epirubicin / cyclophosphamide-based adjuvant chemotherapy in the randomised phase III tAnGo trial for invasive higher risk early stage breast cancer. San Antonio Meeting 2006 (Abstract)

Topics:

- Anthracyclines
- Gemcitabine
- Taxanes

Keywords: Breast cancer, chemotherapy, gemcitabine, paclitaxel, CALGB 9344

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Title: *T*amoxifen and *E*xemestane *A*djuvant *M*ulticentre trial
TEAM

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Summary:

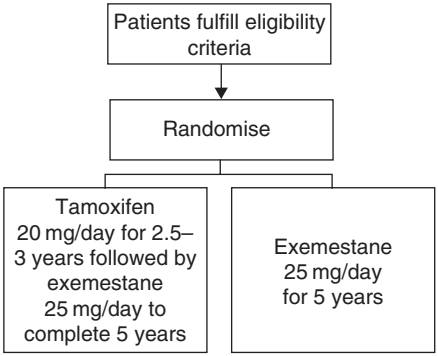
Objective:

- To compare 5 years of adjuvant exemestane treatment with 2.5–3 years of adjuvant tamoxifen followed by exemestane for a total duration of 5 years therapy in postmenopausal women with early breast cancer. Quality of life, pathology and bone substudies are included as part of the British arm of the trial.

Target Accrual:

- 9000 patients worldwide, with 1240 from the UK/Republic of Ireland (RoI).

Scheme:



Update:

- The TEAM trial commenced recruitment in December 2001. The original trial design was to compare 5 years of adjuvant tamoxifen with 5 years of adjuvant exemestane in postmenopausal women with early breast cancer.
- The UK/RoI arm originally closed to recruitment in 2003 having contributed 840 patients to the International TEAM trial. Since the

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start of the trial however a large body of information regarding third-generation aromatase inhibitors in early breast cancer treatment emerged. Of particular relevance, data was published demonstrating a clear advantage in terms of relapse free survival for a sequential strategy in which exemestane is introduced after 2–3 years of prior tamoxifen. As a result of this data a major protocol amendment was introduced into the TEAM study in which patients originally randomized to tamoxifen are now recommended to switch to exemestane after 2.5–3 years of tamoxifen therapy and are reconsented.

- The statistical design of the study has also been amended to encompass two separate primary end points; the first end point will be relapse-free survival before the switch in therapy and the second primary end point will be relapse-free survival following completion of 5 years therapy. To maintain the statistical power of the trial the global recruitment target was expanded and the trial reopened to recruitment in the UK/RoI to enroll an additional 400 patients into the revised trial design.
- In the UK and RoI, 85 centres and 112 consultants have randomized patients into the trial. The trial closed to recruitment in October 2005 and a total of 1275 patients were randomised from the UK/RoI with the international figure standing at over 9000 patients.

Related Publications: None available

Topics:

- Aromatase inhibitors
- Hormonal therapy
- Hormone-receptor positive breast cancer
- Postmenopausal patients
- Tamoxifen

Keywords: Early breast cancer, adjuvant, hormone therapy, aromatase inhibitor, exemestane, tamoxifen, postmenopausal

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Title: Neoadjuvant trial of preoperative exemestane or letrozole ± celecoxib in the treatment of ER positive postmenopausal early breast cancer
NEO-EXCEL

Coordinator(s): Dr M. Grant
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Summary:

- Target accrual: 1000 subjects
- Planned start date: November 2006

Objective:

To determine if exemestance is superior to letrozole as primary neoadjuvant endocrine therapy for early stage ER positive breast cancer in postmenopausal women, and whether the activity of aromatase inhibitors in this setting may be enhanced by the addition of the selective COX-2 inhibitor celecoxib.

- *Primary endpoint*: Objective clinical response (complete response, partial response) to neoadjuvant treatment.
- *Secondary endpoint*: Objective ultrasound-determined response (CR, PR) to neoadjuvant treatment; type of surgery (mastectomy, breast conserving surgery); axillary lymph node involvement at surgery, complete pathological response; local recurrence-free survival; progression-free survival; and overall survival.
- *Translational sub-study:* Biological profiling for prognostic and predictive indicators.

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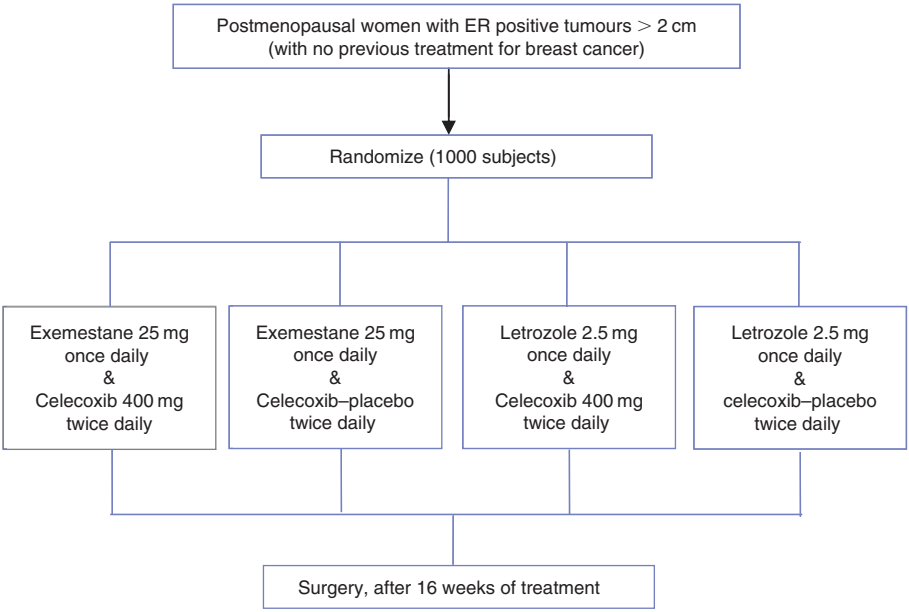
Scheme:



Update: Trial open to recruitment in November 2006.

Related Publications: None available

Topics:

- Aromatase inhibitors
- Breast conservative treatment
- Celecoxib
- Hormonal therapy
- Hormone receptor positive breast cancer
- Postmenopausal patients

Keywords: Aromatase inhibitors, breast cancer, celecoxib, hormone-receptor positive breast cancer, neoadjuvant treatment

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Title: A neoadjuvant study of sequential epirubicin + cyclophosphamide and paclitaxel ± gemcitabine in the treatment of high risk early breast cancer with molecular profiling, proteomics and candidate gene analysis. **Neo-tAnGo**

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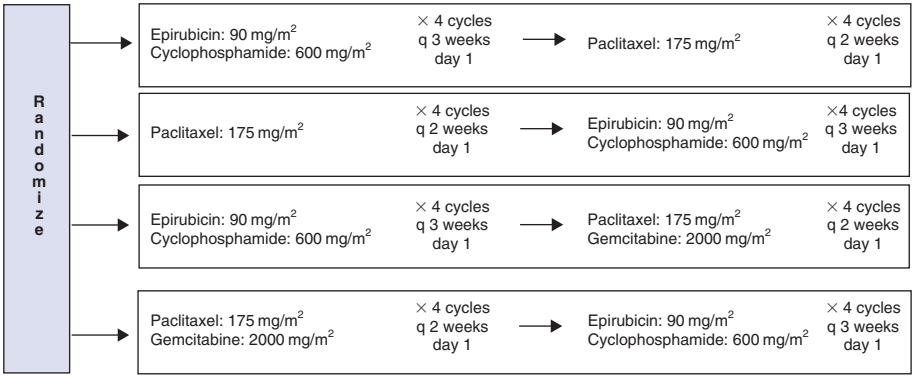
Summary: *Objective:*

- A phase III, randomised trial with two-by-two factorial design addressing both the role of gemcitabine (G) in a sequential neoadjuvant chemotherapy regimen of epirubicin/cyclophosphamide (EC) and paclitaxel (T), and the role of sequencing of these treatment components in terms of short- and long-term outcome in women presenting with high risk early breast cancer.

Target Accrual:

- 800 patients.

Scheme:



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Update:

- Recruitment commenced in January 2005. To date (end of February 2006), 133 patients have been randomized into the study from 21 UK centres. A further 18 centres are open to recruitment. Monthly recruitment is currently averaging 25 patients per month and at this rate of accrual we hope to reach our recruitment target of 800 patients, on time, by the end of 2008.

Related Publications: None available

Topics:

- Anthracyclines
- Gemcitabine
- Taxanes

Keywords: Anthracyclines, breast cancer, gemcitabine, neoadjuvant chemotherapy, taxanes

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