Patient Eligibility/Exclusion

Patients who can take part in the *TEAM* study must fulfil the following criteria:

- Histologically/ cytologically confirmed early adenocarcinoma of the breast completely excised by surgery with curative intent (Ro)
- Postmenopausal
- Node positive **OR** Node negative with Grade II or III greater than or equal to 1cm (Node negative, Grade I tumours less than 3cm are <u>not</u> eligible,)
- ER and/or PgR status positive
- Patients on hormone replacement therapy (HRT) that was discontinued at least 4 weeks prior to randomisation are eligible for inclusion
- Neoadjuvant/peri-operative hormone therapy (tamoxifen) of 4 weeks or less duration
- Adequate haematological, renal and hepatic function
- ECOG performance status 0,1 or 2
- Randomisation within 10 weeks of completing primary surgery OR of completing adjuvant chemotherapy treatment (all CT must have been completed prior to randomisation)
- No patients whose chemotherapy was started more than 10 weeks after completion of primary surgery
- No patients who have received neoadjuvant chemotherapy
- No positive supraclavicular nodes
- No evidence of distant metastases
- No patients with severe osteoporosis
- No uncontrolled cardiac disease including unstable angina, CHF or arrhythmia requiring medical therapy or with a history of myocardial infarction within the past 3 months or any other serious concomitant disease
- No concomitant malignancies except for adequately treated carcinoma *in situ* of the uterine cervix or basal cell carcinoma of the skin. Patients with other malignancies must be disease free for at least 5 years

In addition to the above criteria, common queries relate to the following

- A chest X -ray within 6 months of diagnosis is only necessary *if clinically indicated*
- Mammography, blood chemistry and haematology should be assessed according to *local policy*
- After randomisation patients will visit the centre every 3 months for the first year, thereafter they will be followed according to local policy
- Tamoxifen is prescribed according to local policy but the exemestane can only be prescribed through hospital pharmacies
- The first Quality of Life study is not part of the current protocol (Version 6 27th Oct 2005)
- Radiotherapy can be given either *before OR after* randomisation
- Trial treatment should begin not more than 5-7 days after randomisation
- Pathology sub-study is optional for the patient.
- Pathology requests are done through the *TEAM* Study Office directly

Trial Payments

Investigator payment of £400 per patient randomised

Pathologist payment of £25 per tumour block received