**SEQUENCING OF CHEMOTHERAPY AND RADIOTHERAPY IN ADJUVANT BREAST CANCER**

**INTRODUCTION**

*SECRA* is a prospective, multicentre, randomised study comparing two different methods of sequencing chemotherapy (CT) and radiotherapy (RT) for women with a clear indication for both as adjuvant treatment following definitive surgery for early stage breast cancer. The study is primarily designed to answer the following questions:

- Can local control be improved by synchronous delivery of CT and RT?
- Can these two treatment modalities be given together safely?

The intention is to randomise 2250 women.

**TRIAL DESIGN**

Women with early breast cancer having adjuvant CT and RT following breast conserving surgery or mastectomy

- Confirm eligibility
- Prescribe appropriate CT and RT regimens
- Decide if a boost dose will be given
- Obtain informed consent

Randomise

Sequential Schedule

CT → RT

Synchronous Schedule

CT → RT → CT

Annual follow-up for 5 years (relapse and survival status)

**PERMITTED TREATMENT OPTIONS**

**Chemotherapy**
- CMF (iv or oral)
- Anthracycline + CMF
- Sutton Mitoxantrone and Methotrexate
- Mitomycin-C, Mitoxantrone and Methotrexate

**Radiotherapy**
- 39 Gy in 13 Fractions over 5 weeks
- 40 Gy in 15 fractions over 3 weeks
- 45 Gy in 20 fractions over 4 weeks
- 46 Gy in 23 fractions over 4 1/2 weeks
- 50 Gy in 25 fractions over 5 weeks

**ENDPOINTS**

- Local recurrence rates at 5 years
- Survival
- Distant and overall recurrence rates
- Toxicity and late effects of treatment

**MAIN ELIGIBILITY CRITERIA**

- Complete excision of histological proven invasive breast carcinoma
- Clear indication for both adjuvant CT and RT
- The intended schedules can be given synchronously
- Medically fit enough to complete CT and RT
- The patient has given written informed consent
- No prior CT
- No prior malignancy

**DETAILED SUB-STUDY**

In order to collect more complex data, a subset of 300 patients are invited to take part in a Detailed Sub-Study. Differences in toxicity, treatment delay, dose intensity of CT, quality of life and cosmesis will be compared. Well being during treatment and over a two-year period will be assessed, by use of questionnaires and diary sheets.

**FOR ADDITIONAL INFORMATION CONTACT**

Dr. Sarah Bowden
Cancer Research UK Clinical Trials Unit,
Institute for Cancer Studies,
The University of Birmingham, Edgbaston, Birmingham B15 2TT
Tel: 0121 414 4371; Fax 0121 414 3700;
e-mail BTT@bham.ac.uk or s.j.bowden@bham.ac.uk