

# Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast cancer



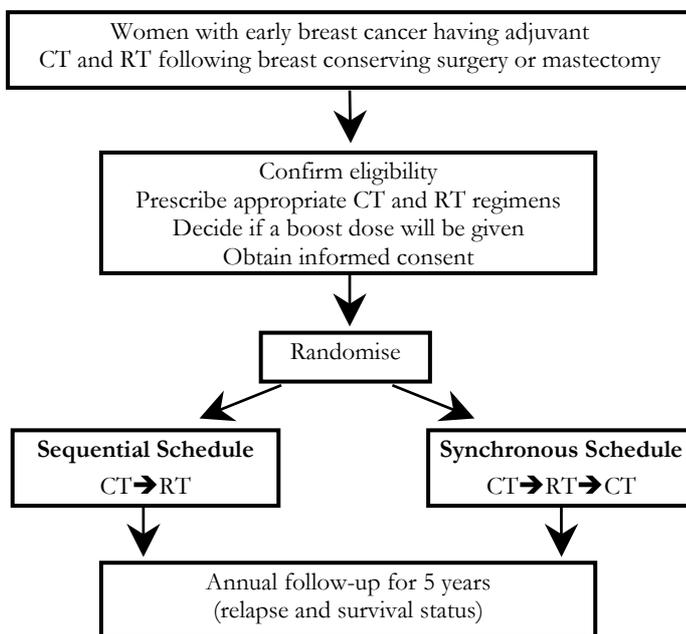
## INTRODUCTION

**SECRAB** 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



## 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 4½ 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 [BT@bham.ac.uk](mailto:BT@bham.ac.uk) or [s.j.bowden@bham.ac.uk](mailto:s.j.bowden@bham.ac.uk)