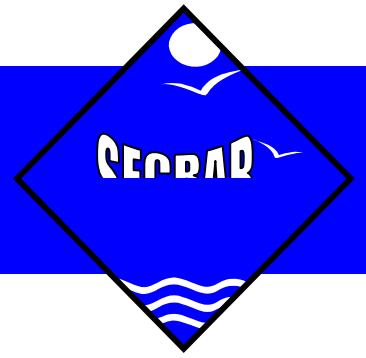


Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast cancer



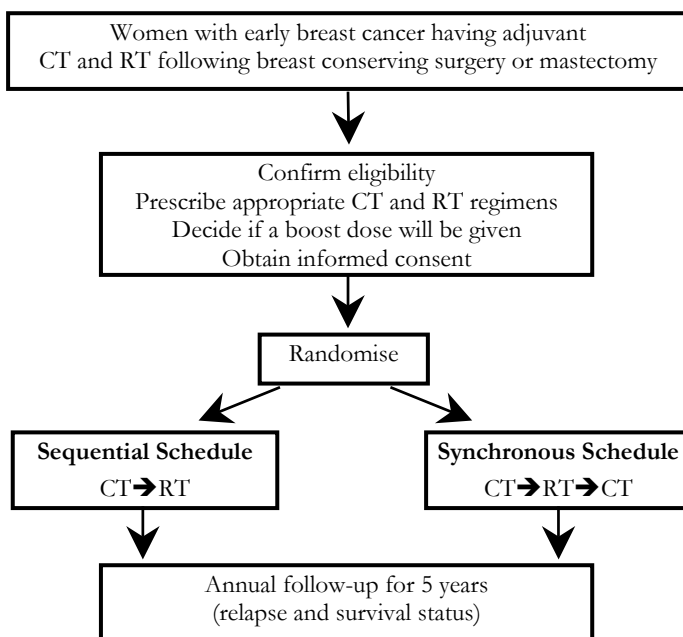
INTRODUCTION

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 or s.j.bowden@bham.ac.uk