

# Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast cancer

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00003893

**Protocol serial number**  
BR3015

## Study information

**Scientific Title**

Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast cancer

**Acronym**

SECRAB

**Study objectives**

To answer reliably two questions in the timing of delivery of chemotherapy and radiotherapy in the adjuvant treatment of early breast cancer:

1. Can local control be improved by synchronous delivery of adjuvant chemotherapy and radiotherapy thereby not delaying the administration of either modality?
2. Can synchronous chemotherapy and radiotherapy be given safely without significant enhancement of acute or late toxicity, without compromising on dose intensity of either modality and without adversely affecting quality of life or cosmesis?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

West Midlands Research Ethics Committee, 09/04/1998, MREC/98/7/16

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Breast cancer

**Interventions**

Two arms:

Arm 1 - Synchronous treatment (Chemotherapy - Radiotherapy - Chemotherapy)

Arm 2 - Sequential treatment (Chemotherapy - Radiotherapy)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Local tumour recurrence rates at 5 and 10 years

**Key secondary outcome(s)**

1. Distant and overall recurrence rates
2. Survival at 5, 10 and 15 years

3. Acute toxicity causing significant treatment delay or dose reduction
4. Other late effects of treatment

**Completion date**

25/03/2004

## Eligibility

**Key inclusion criteria**

1. Histological diagnosis of invasive breast carcinoma (unilateral if participating in the Cosmesis Study)
2. Wide local excision or mastectomy with macroscopic complete excision of clinically early stage disease and no evidence of metastases
3. There is a clear indication for both adjuvant chemotherapy and radiotherapy, or the patient has been randomised to these treatments in another study
4. The intended schedules can be given synchronously and the patient is considered suitable to receive either treatment sequence
5. Medically fit enough to complete chemotherapy and radiotherapy, with adequate cardiac, renal, hepatic and bone marrow function
6. The patient has given written informed consent
7. No prior chemotherapy (other than hormone manipulation)
8. No prior malignancy (except skin basal/squamous cell or in situ carcinoma)
9. Not currently pregnant or lactating, no intention of pregnancy during treatment
10. No other medical or social contra-indication to entry and follow-up

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

N/A

**Date of first enrolment**

02/07/1998

**Date of final enrolment**

25/03/2004

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**CRUK Clinical Trials Unit**  
Birmingham  
United Kingdom  
B15 2TT

## Sponsor information

**Organisation**  
University Hospitals Birmingham NHS Foundation Trust (UK)

**ROR**  
<https://ror.org/014ja3n03>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Cancer Research UK (UK)

**Alternative Name(s)**  
CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2006	25/01/2019	Yes	No
<a href="#">Plain English results</a>				No	Yes