

Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Bowden

Contact details
CRUK Clinical Trials Unit
Institute for Cancer Studies
The University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 4371
BTT@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003893

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Local tumour recurrence rates at 5 and 10 years

Secondary outcome measures

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

Overall study start date

02/07/1998

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

Age group

Adult

Sex

Female

Target number of participants

2298

Key exclusion criteria

N/A

Date of first enrolment

02/07/1998

Date of final enrolment

25/03/2004

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

CRUK Clinical Trials Unit

Birmingham

United Kingdom

B15 2TT

Sponsor information**Organisation**

University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details

Research & Development

Nuffield House

Queen Elizabeth Hospital

Edgbaston

Birmingham

England

United Kingdom

B15 2TH

Sponsor type

Hospital/treatment centre

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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	01/04/2006	25/01/2019	Yes	No