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Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast cancer

Submission date	Recruitment status	[_] Prospectively registered
01/07/2001	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2019	Cancer	

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

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?
Results article	results	01/04/2006	25/01/2019	Yes	No
Plain English results				No	Yes