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Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00003893

Secondary identifying numbers

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

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
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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