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A collaborative trial to evaluate the role of radiotherapy and adjuvant tamoxifen in the conservative management of clinical stage I and II breast cancer

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 23/02/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
- - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BR3002

Study information

Scientific Title
A collaborative trial to evaluate the role of radiotherapy and adjuvant tamoxifen in the conservative management of clinical stage I and II breast cancer

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Following surgery to remove the tumour patients are randomised into one of six treatment groups:
1. Group A: Tamoxifen daily for 2 years
2. Group B: Tamoxifen daily until recurrence
3. Group C: Short radiotherapy plus tamoxifen daily for 2 years
4. Group D: Short radiotherapy plus tamoxifen daily until recurrence
5. Group E: Long radiotherapy plus tamoxifen daily for 2 years
6. Group F: Long radiotherapy plus tamoxifen daily until recurrence

SYSTEMIC TREATMENT: Tamoxifen 20 mg daily to start immediately following surgery

POST-OPERATIVE RADIOTHERAPY:
Short Radiotherapy: 40 Gy in fifteen daily fractions given over 3 weeks with a supplementary boost to the local tumour site of 15 Gy in five daily fractions.
Long Radiotherapy: 50 Gy in twenty-five daily fractions given over 5 weeks with a supplementary boost to the local tumour site of 15 Gy in five daily fractions.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tamoxifen

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1997

Completion date
31/12/1999

Eligibility

Key inclusion criteria
1. Histologically proven adenocarcinoma of breast
2. Tumour size <5 cm
3. No clinically palpable axillary nodes
4.. Have had an operation resulting in a cosmetically satisfactory breast
5. No evidence of systemic metastases
6. No previous treatment for a malignancy by radiotherapy or chemotherapy
7. Patients with Paget's disease of the nipple, bilateral breast cancer or lymphoedema of the breast are excluded
8. No previous or co-existing malignancies, except basal cell carcinoma of skin and in-situ carcinoma of cervix
9. Patients must be fit enough to receive any of the specified treatments

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1997

Date of final enrolment
31/12/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research 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