ISRCTN99513870 https://doi.org/10.1186/ISRCTN99513870

United Kingdom randomised trial for the management of screen-detected ductal carcinoma in situ (DCIS) of the breast

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 03/02/2011	**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

Secondary identifying numbers

UKCCCRDCIS

Study information

Scientific Title

Study objectives
1. In patients with mammographically detected DCIS to compare the effectiveness of complete local excision (CLE) alone with CLE followed by radiotherapy to the residual ipsi-lateral breast tissue and/or tamoxifen 20 mg daily for five years, in reducing the incidence of subsequent invasive carcinoma of the breast
2. To monitor contralateral disease within randomised arms of the trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 2 x 2 factorial trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breast Cancer

Interventions
1. Treatment A: Complete local excision with no further initial local or systemic therapy.
2. Treatment B: Complete local excision followed by supervoltage radiotherapy to the residual breast tissue to a dose of 50 Gy given in twenty-five fractions over five weeks. Radiotherapy to commence no later than eight weeks after the final surgical procedure.
3. Treatment C: Complete local excision followed by tamoxifen 20 mg daily for five years. Tamoxifen therapy to commence no later than eight weeks after the final surgical procedure.
4. Treatment D: Complete local excision followed by radiotherapy and tamoxifen (as above). If wished patients may be randomised for one treatment only, i.e. tamoxifen or radiotherapy, in which case the other treatment may electively be given or not given.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Local control of disease
2. Any involvement of contralateral breast
3. Overall survival and cause-specific mortality

Secondary outcome measures
Not provided at time of registration

Overall study start date
09/05/1990

Completion date
30/08/1996

Eligibility

Key inclusion criteria
1. Unilateral or bilateral DCIS which is cosmetically suited to breast conservation, which has been detected as a result of attendance at a screening centre, which is without evidence of invasion, and which has been completely excised as determined by free margins on histological examination
2. Patients with similarly defined DCIS lesions, in whom the diagnosis of DCIS has been made as a result of mammograms taken following referral to a diagnostic clinic
3. Patients with Paget's disease of the nipple, lobular carcinoma in situ of the breast or atypical hyperplasia in the absence of DCIS are excluded
4. Pathologist must be able to state that the excision margins are clear, even after re-excision
5. No axillary lymph node involvement
6. Able to receive either treatment

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1,000

Key exclusion criteria

1. Involved excision margins
2. Paget's Disease
3. Nodal spread

Date of first enrolment
09/05/1990

Date of final enrolment
30/08/1996

Locations

Countries of recruitment
Australia

England

New Zealand

United Kingdom

Study participating centre
Wolfson Institute of Preventive Medicine,
London
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EC1M 6BQ

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
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WC2A 3PX
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Sponsor type
Charity

Website

http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Research organisation

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

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Results article	results	01/01/2011		Yes	No