

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

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/02/2011	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

Australia

New Zealand

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

## Sponsor information

**Organisation**  
Cancer Research UK (CRUK) (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, Cancer Research UK (CRUK), 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, Medical Research Committee and Advisory Council, MRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### 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?
<a href="#">Results article</a>	results	01/01/2011		Yes	No