

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/02/2011	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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
United Kingdom
EC1M 6BQ

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

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