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# Randomised trial testing observation (no radiotherapy) against radiotherapy in women with low-risk completely excised oestrogen receptor positive ductal carcinoma in situ of the breast on adjuvant endocrine therapy

**Submission date**
11/02/2004

**Recruitment status**
No longer recruiting

**Registration date**
13/04/2004

**Overall study status**
Completed

**Last Edited**
02/10/2012

**Condition category**
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

**ClinicalTrials.gov (NCT)**
NCT00077168

**Protocol serial number**
N0226152511

# Study information

**Scientific Title**

**Acronym**
NCRI/BASO UK DCIS II Trial

**Study objectives**
To determine, in a randomised controlled trial, the effects of withholding radiotherapy (in terms of recurrence and quality of life) after complete removal of oestrogen receptor (ER) positive low-risk precancerous change in the breast (ductal carcinoma in situ [DCIS]) and in the presence of adjuvant endrocrine therapy.

**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

**Study type(s)**
Treatment

**Health condition(s) or problem(s) studied**
Ductal carcinoma in situ

**Interventions**
All patients will receive endocrine therapy: either as part of the IBIS II trial (which randomises between tamoxifen or anastrozole), otherwise all non-IBIS II patients will be prescribed tamoxifen 20 mg/day (for five years).

2000 eligible patients will be randomised in a ratio of 1:1 to either:
1. Radiotherapy plus tamoxifen or anastrozole
2. No radiotherapy plus tamoxifen or anastrozole

**Intervention Type**
Drug

**Phase**
Not Specified

### Drug/device/biological/vaccine name(s)
Tamoxifen or anastrozole

### Primary outcome(s)
Proportion of patients developing a recurrence in the affected breast five years after primary surgery.

### Key secondary outcome(s))
Not provided at time of registration.

### Completion date
13/10/2009

## Eligibility

### Key inclusion criteria
1. Unifocal DCIS without an invasive component. Patients with microinvasion (defined as one or more foci of invasion each less than 1 mm) may be included
2. Complete microscopic excision with a MINIMUM radial margin of 1 mm
3. ER positive or progesterone receptor (PgR) positive (either more than 10% tumour cells staining for receptor or a cut point of more than two)
4. Maximum microscopic tumour diameter must be less than 30 mm (less than 15 mm if grade III)
5. Primary surgery within six months of randomisation
6. The majority of women will be postmenopausal and all should be between the ages of 50 and 75 years. Postmenopausal status is defined as meeting one or more of the following criteria:
6.1. Aged over 60
6.2. Bilateral oophorectomy
6.3. Aged under 60 with a uterus and amenorrhoea for at least 12 months
6.4. Aged under 60 without a uterus and with follicle-stimulating hormone (FSH) more than 20 IU /L
6.5. Off Hormone Replacement Therapy (HRT) for more than four weeks and with an FSH more than 20 IU/L. Premenopausal and perimenopausal women (over 50 years of age) are eligible for DCIS II but not for IBIS II study
7. Fully informed signed consent
8. Patient available for long-term follow up

All post-menopausal women will potentially be eligible for IBIS II.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
Female

### Key exclusion criteria
1. Aged under 50 years
2. ER negative DCIS or PgR negative (less than 10% cell staining positive immunohistochemically or a cutpoint of less than two)
3. Any previous cancer in the past five years (except non-melanoma skin cancer or in situ cancer of the cervix)
4. Current treatment with anti-coagulants
5. Previous deep vein thrombosis or pulmonary embolus
6. Previous tamoxifen or raloxifene use for more than three months
7. Any woman with unexplained postmenopausal bleeding
8. Tumour incompletely excised
9. DCIS lesions equals 30 mm maximum microscopic diameter (more than 15 mm if grade III)
10. Patient treated by mastectomy
11. Patients unable to undergo follow-up
12. Any condition precluding full dose radiotherapy to the breast

### Date of first enrolment
13/10/2004

### Date of final enrolment
13/10/2009

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**South Manchester University Hospital**
Manchester
United Kingdom
M23 9LT

## Sponsor information

### Organisation
Sponsor not defined - Record supplied by Institute of Cancer Research (UK)

## Funder(s)

### Funder type

Charity

**Funder Name**
Cancer Research UK (CRUK) (UK) (ref: C1491/A4589)

**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, 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? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2011 | | Yes | No |