ISRCTN22614215 https://doi.org/10.1186/ISRCTN22614215

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/04/2004	**Overall study status** Completed	
Last Edited 02/10/2012	**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
NCT00077168

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Proportion of patients developing a recurrence in the affected breast five years after primary surgery.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
13/10/2004

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

Age group
Senior

Sex
Female

Target number of participants
2000

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
England

United Kingdom

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)

Sponsor details
c/o Institute of Cancer Research
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Not defined

Funder(s)

Funder type
Charity

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

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