ISRCTN31514446 https://doi.org/10.1186/ISRCTN31514446

# The NCRI adjuvant breast cancer (ABC) trial

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|---|---|---|
| **Submission date**<br>06/04/2000 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>06/04/2000 | **Overall study status**<br>Completed | |
| **Last Edited**<br>07/05/2013 | **Condition category**<br>Cancer | |

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

**Study website**
http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/2413_disease.shtml

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**
NCT00002582

### Secondary identifying numbers
G9437812

# Study information

### Scientific Title

### Acronym
ABC

### Study objectives
To determine the value of adding cytotoxic chemotherapy and/or (in premenopausal women) ovarian suppression to prolonged tamoxifen in women with early breast cancer.

### 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)
Not specified

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Breast cancer

### Interventions
Cytotoxic chemotherapy and/or (in premenopausal women) ovarian suppression and prolonged tamoxifen/tamoxifen

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
The main endpoint used for evaluation of treatment efficacy will be overall survival based on all cause mortality. Relapse-free survival, breast cancer mortality and cardiovascular mortality will also be compared. In a subset of patients there will be a detailed assessment of quality of life. Health economic consequences will also be determined. Ongoing biological predictors of therapeutic response studies, funded by CRUK and BCC.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/1993

### Completion date
30/09/2005

## Eligibility

### Key inclusion criteria
All women with early invasive breast cancer requiring adjuvant systemic therapy are eligible for the trial providing they have:
1. Early (operable) breast cancer
2. Histological confirmation of invasive carcinoma
3. No previous malignancy (except carcinoma in situ [CIS] cervix or basal cell carcinoma)
4. Received no previous systemic treatment for their disease
5. Given consent and available for subsequent follow-up

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
6000

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
01/01/1993

### Date of final enrolment
30/09/2005

# Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### Section of Epidemiology
Sutton
United Kingdom
SM2 5NG

# Sponsor information

### Organisation
Institute of Cancer Research (UK)

### Sponsor details
123 Old Brompton Road
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abc-icrctsu@icr.ac.uk

### Sponsor type
Research organisation

### Website
http://www.icr.ac.uk/

### ROR
https://ror.org/043jzw605

# Funder(s)

### Funder type
Research council

### Funder Name

Medical Research Council (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 | 04/04/2007 | | Yes | No |
| Results article | results | 14/03/2012 | | Yes | No |