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The NCRI adjuvant breast cancer (ABC) trial

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

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)
NCT00002582

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
Institute of Cancer Research (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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes