

The NCRI adjuvant breast cancer (ABC) trial

Submission date 06/04/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/05/2013	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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Contact details

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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

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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