

Cancer Research Campaign adjuvant breast trial for patients under 50

Submission date 01/07/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00002460

Protocol serial number
CRCBCTG9

Study information

Scientific Title
Cancer Research Campaign adjuvant trial

Study objectives

Not provided at time of registration

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)**Health condition(s) or problem(s) studied**

Breast cancer

Interventions

Following surgery (local excision or mastectomy) with or without additional primary therapy patients are randomised to either:

1. Group A: No further treatment.
2. Group B: Adjuvant tamoxifen, 20 mg daily for 2 years. Treatment to start as soon as possible following surgery.
3. Group C: Zoladex, 3.6 mg depot/month for 2 years. Treatment to start as soon as possible following surgery.
4. Group D: Tamoxifen 20 mg daily and Zoladex 3.6 mg depot/month both for 2 years. Treatment to start as soon as possible following surgery.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

22/03/1999

Eligibility**Key inclusion criteria**

1. Aged < 50 years
2. Operable breast cancer, that is clinically T1,T2 or T3,N0 or N1,M0
3. No evidence of metastases
4. Normal renal, hepatic function and full blood counts, including platelets
5. Patients with bilateral tumours are not eligible
6. No concomitant hormonal therapy or chemotherapy
7. No hormonal therapy in the last 6 weeks
8. No previous malignancy, except basal or squamous cell carcinoma of the skin or in situ carcinoma of the cervix adequately cone biopsied
9. Fit to receive either treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1994

Date of final enrolment

22/03/1999

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

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

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	10-year follow-up results	01/06/1992		Yes	No
Protocol article	protocol	01/06/1989		Yes	No