ISRCTN52689949 https://doi.org/10.1186/ISRCTN52689949

Cancer Research Campaign adjuvant breast trial for patients under 50

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 08/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes