

Cancer Research Campaign adjuvant breast trial for patients under 50

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|--|---|---|
| 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
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002460

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

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

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1994

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

Age group

Not Specified

Sex

Female

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

Sponsor details

PO Box 123

Lincoln's Inn Fields

London

United Kingdom

WC2A 3PX

+44 (0)207 317 5186

kate.law@cancer.org.uk

Sponsor type

Charity

Website

<http://www.cancer.org.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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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