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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
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