ISRCTN29547753 https://doi.org/10.1186/ISRCTN29547753

Cancer Research Campaign adjuvant breast trial for patients over the age of 50

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 10/03/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
- -

Contact details
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Additional identifiers

Protocol serial number
OVER50

Study information

Scientific Title
Cancer Research Campaign adjuvant breast trial for patients over the age of 50

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)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Patients receive primary surgical and irradiation treatments as are felt appropriate and are started on tamoxifen 20 mg daily.

Patients event-free and consenting at 2 years are randomised into one of two treatment groups:
1. Group A: Stop tamoxifen
2. Group B: Continue tamoxifen therapy for a further 3 years

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tamoxifen

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
03/12/2000

Eligibility

Key inclusion criteria
1. Aged >50 years and <70 years (revised to <80 years in February 1991)
2. Operable breast cancer (clinically T1, T2 or T3, N0 or N1, M0)
3. No evidence of metastases

4. Normal renal and 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 previous malignancy, except basal or squamous cell carcinoma of the skin or in situ carcinoma of the cervix adequately cone biopsied
8. Patients whose axillary nodes demonstrate deep fixity are not eligible
9. Patients whose primary cancer is fixed to the underlying muscle or chest wall, or those with ulceration, skin infiltration, peau d'orange or satellite skin nodules are not eligible
10. Fit to receive either treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1995

Date of final enrolment
03/12/2000

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC Clinical Trials Unit
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