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

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

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

- -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

#### 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