

A trial to study the place of surgery in elderly women with breast cancer treated by tamoxifen

Submission date 01/07/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input 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 13/06/2014	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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222 Euston Road
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRCBCTG6

Study information

Scientific Title

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

Interventions

1. Group A: Optimal surgery plus tamoxifen, 20 mg twice daily
2. Group B: Tamoxifen, 20 mg twice daily

All patients receive tamoxifen until there is evidence of progressive disease.

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

01/01/1995

Completion date

31/12/1997

Eligibility

Key inclusion criteria

1. Aged >70 years
2. Histological, cytological or unequivocal mammographic confirmation of carcinoma of the breast
3. Operable breast cancer
4. No metastases
5. No previous malignancy, except skin cancer or adequately treated in situ carcinoma of the cervix
6. Fit and willing to receive either treatment

Participant type(s)

Patient

Age group

Senior

Sex

Female

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Patients with bilateral breast cancer are excluded
2. Patients with Paget's disease without a palpable lump, in situ carcinoma or an impalpable lesion shown on mammograph alone are excluded

Date of first enrolment

01/01/1995

Date of final enrolment

31/12/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details

MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Sponsor type

Government

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

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?
Results article	results	01/08/1997		Yes	No