ISRCTN43697410 https://doi.org/10.1186/ISRCTN43697410

Scottish Chemo-Endocrine Trial D

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 25/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002579

Secondary identifying numbers
SCTN-BR9403; EORTC 10901

Study information

Scientific Title
Tamoxifen following combination chemotherapy in treating women with operable invasive breast cancer

Study objectives
The aim of the trial is to assess whether adjuvant Tamoxifen given after post operative chemotherapy for primary breast cancer adds to the disease free at overall survival advantage which results from adjuvant chemotherapy alone. In Scotland, Tamoxifen will be given for 5 years whereas in other countries the duration will be 3 years. (Part of the Scottish Chemo-Endocrine Trial D (EORTC Trial 10901) - UK CCCR ABC trial framework)

As of 05/08/09 this record has been extensively updated. All updates can be found under the relavent field with the above update date. Please also note the start and end dates of this trial have been changed from 01/01/1999 and 15/05/1999 respectively. Funding information has been corrected from Scottish Therapy Network to Scottish Cancer Therapy Network.

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)
Treatment

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
Current information as of 05/08/09:
Patients are stratified by age and by participating institution. All patients undergo surgical resection with local radiation therapy, as appropriate. Within 4 weeks of surgery, patients receive cyclophosphamide, methotrexate, and fluorouracil (CMF) every 3 weeks for 6 courses. Radiotherapy is given within 4 weeks of completion of CMF. Before beginning the last course of CMF, patients are randomized to receive either oral tamoxifen daily for 5 years or no further

therapy. Patients are followed every 6 months for 5 years, then yearly. Hormone therapy is prohibited except as specified above and except for short-term hormone replacement therapy for severe unresponsive menopausal symptoms.

Initial information at time of registration:
All patients receive chemotherapy, CMF (Cyclophosphamide, Methotrexate and 5-Fluorouracil) repeated every three weeks for six cycles.

Patients are then randomised to one of two treatment groups:
1. Group A: Tamoxifen, 20 mg daily for five years
2. Group B: No further treatment

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Tamoxifen, cyclophosphamide, methotrexate, and fluorouracil

Primary outcome measure
(Added 05/08/09) Disease free at overall survival

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1998

Completion date
30/06/2004

Eligibility

Key inclusion criteria
1. Pre- or post-menopausal
2. Histologically confirmed palpable unilateral invasive breast cancer of TNM (Tumour, Node, Metastasis) stages T1-T3, N0-N1 and M0, for whom adjuvant chemotherapy is considered an essential part of initial therapy
3. A bilateral mammography to have been performed within the year prior to randomisation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
(Added 05/08/09) Approximately 2,000 patients will be required. Data on patients entered in Scotland as part of this study will be pooled with data from the EORTC-10901 study.

Key exclusion criteria
1. Patients with in situ carcinoma only, including Paget's disease of the nipple without underlying invasion
2. Presence of distant metastases
3. Patients currently receiving tamoxifen
4. Prior history of other malignancy, other than adequately treated basal or squamous cell carcinoma of skin
5. Other contraindications to treatment

Date of first enrolment
01/07/1998

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Scottish Cancer Therapy Network (UK)

Sponsor details
Trinity Park House
South Trinity Road
Edinburgh
United Kingdom
EH5 3SQ

Sponsor type

Research organisation

Funder(s)

Funder type
Other

Funder Name
Scottish Cancer Therapy Network (UK)

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