# Scottish Chemo-Endocrine Trial D

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

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

## 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