ISRCTN66949472 https://doi.org/10.1186/ISRCTN66949472

# Tamoxifen and Exemestane Trial

**Submission date**
18/06/2010

**Recruitment status**
No longer recruiting

**Registration date**
18/06/2010

**Overall study status**
Completed

**Last Edited**
20/05/2024

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-different-hormone-therapies-for-pre-menopausal-women-with-breast-cancer

**Study website**
http://www.ibcsg.org/public/general_pages/trials/open/trial_25-02.shtml

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**
2004-000168-28

**IRAS number**

**ClinicalTrials.gov number**

NCT00066703

### Secondary identifying numbers
1306

# Study information

### Scientific Title
The role of ovarian function suppression (OFS) in premenopausal women with hormone responsive early breast cancer: tamoxifen versus exemestane - a multicentre randomised interventional trial

### Acronym
TEXT

### Study objectives
Tamoxifen versus Exemestane Trial (TEXT) is one of three trials being launched by the International Breast Cancer Study Group to determine the role of ovarian function suppression (OFS) in pre-menopausal women with hormone responsive early breast cancer.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 03/11/2004, South West- Cornwall and plymouth (cornwallandplymouth.rec@hra.nhs.uk, Bristol, CB22 2QQ, United Kingdom; +44 (0)207 104 8143; cornwallandplymouth.rec@hra.nhs.uk), ref: 04/MRE06/04

### Study design
Multicentre randomized interventional treatment trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
GP practice

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

### Interventions
Group A:
Randomisation prior to receiving any adjuvant systemic therapy. Triptorelin for 5 years plus. Chemotherapy (CT), if used, should begin at the same time as triptorelin. Use of CT may be determined by randomisation in the PERCHE trial or by investigator/patient choice. Tamoxifen will then be provided for 5 years. Tamoxifen should start after adjuvant chemotherapy has been completed or approximately six to eight weeks after the initiation of triptorelin, whichever is later.

Group B:
Randomisation prior to receiving any adjuvant systemic therapy. Triptorelin for 5 years plus. Chemotherapy (CT), if used, should begin at the same time as triptorelin. Use of CT may be determined by randomisation in the PERCHE trial or by investigator/patient choice. Exemestane will then be provided for 5 years. Exemestane should start after adjuvant chemotherapy has been completed or approximately six to eight weeks after the initiation of triptorelin, whichever is later.

Follow up length: 120 months
Study entry: registration and one or more randomisations

### Intervention Type
Drug

### Phase
Phase III

### Drug/device/biological/vaccine name(s)
Tamoxifen, exemestane

### Primary outcome measure
Disease-free survival

### Secondary outcome measures
1. Causes of death without cancer event
2. Incidence of second (non-breast) malignancies
3. Late side effects of early menopause
4. Overall survival
5. Quality of life
6. Sites of first treatment failure
7. Systemic disease-free survival

### Overall study start date
07/11/2003

### Completion date
21/02/2024

## Eligibility

### Key inclusion criteria

1. Pre-menopausal women (oestradiol [E2] levels in the premenopausal range), aged above 18 years
2. Histologically proven, resected breast cancer. Pathology material should be available for submission for central review.
3. Hormone receptor positive (HR+) tumour. HR must be determined using immunohistochemistry (IHC): oestrogen receptor (ER) and/or progesterone receptor (PgR) greater than or equal to 10%.
4. Tumour confined to the breast and axillary nodes without detected metastases elsewhere with the exception of tumour detected in the internal mammary chain nodes by sentinel node procedure
5. Proper surgery (total mastectomy or breast conserving procedure plus radiation) for primary disease with no known clinical residual disease
6. Axillary lymph node dissection or negative axillary sentinel node biopsy
7. Written informed consent and accessible for follow-up
8. Patients must be informed of and agree to data and tissue transfer and handling, in accordance with national data protection guidelines

## Participant type(s)
Patient

## Age group
Adult

## Lower age limit
18 Years

## Sex
Female

## Target number of participants
Planned sample size: 1845

## Total final enrolment
2672

## Key exclusion criteria
1. Postmenopausal
2. Distant metastatic disease
3. Locally advanced inoperable breast cancer
4. Bilateral invasive breast cancer
5. Positive final margins
6. Clinically detectable residual axillary disease
7. History of previous ipsilateral or contralateral invasive breast cancer
8. Previous or concomitant malignancy except adequately treated basal/squamous cell carcinoma of the skin, in-situ carcinoma of the cervix or bladder, contralateral or ipsilateral in-situ breast cancer
9. Other non-malignant systemic diseases that would prevent prolonged follow-up
10. Patients who have had a bilateral oophorectomy or ovarian irradiation
11. History of noncompliance to medical regimens or considered potentially unreliable
12. Previous or concomitant malignancy except adequately treated basal/squamous cell carcinoma of the skin, in-situ carcinoma of the cervix or bladder, contralateral or ipsilateral in-

situ breast cancer
13. Other non-malignant systemic diseases that would prevent prolonged follow-up

### Date of first enrolment
07/11/2003

### Date of final enrolment
31/05/2008

## Locations

### Countries of recruitment
England

Germany

Sweden

United Kingdom

### Study participating centre
**Clinical Trials & Statistics Unit (ICR-CTSU)**
Sutton
United Kingdom
SM2 5NG

## Sponsor information

### Organisation
International Breast Cancer Study Group (IBCSG)

### Sponsor details
Effingerstrasse 40
Bern
Switzerland
3008

### Sponsor type
Research organisation

### Website
http://www.ibcsg.org/Pages/default.aspx

### ROR
https://ror.org/05b2gms10

# Funder(s)

### Funder type
Research organisation

### Funder Name
International Breast Cancer Study Group

# 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? |
|---|---|---|---|---|---|
| Plain English results | | | | No | Yes |
| Basic results | | | 09/09/2019 | No | No |
| Results article | results | 10/07/2014 | 09/09/2019 | Yes | No |