

# Tamoxifen and Exemestane Trial

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>18/06/2010   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>18/06/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>20/05/2024       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> 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>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00066703

### Clinical Trials Information System (CTIS)

2004-000168-28

### Protocol serial number

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

## Primary study design

Interventional

## Study design

Multicentre randomized interventional treatment trial

## Study type(s)

Treatment

## 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(s)**

Disease-free survival

### **Key secondary outcome(s)**

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

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**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**

United Kingdom

England

Germany

Sweden

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

## Sponsor information

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

**ROR**  
<https://ror.org/05b2gms10>

## Funder(s)

**Funder type**  
Research organisation

**Funder Name**  
International Breast Cancer Study Group

## Results and Publications

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? |
|---------------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>       | results       | 10/07/2014   | 09/09/2019 | Yes            | No              |
| <a href="#">Basic results</a>         |               |              | 09/09/2019 | No             | No              |
| <a href="#">Plain English results</a> |               |              |            | No             | Yes             |
|                                       | Study website |              |            |                |                 |

[Study website](#)

11/11/2025

11/11/2025

No

Yes