

Tamoxifen and Exemestane Trial

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

Mr Mark Webster-Smith

Contact details

Clinical Trials & Statistics Unit (ICR-CTSU)
Section of Clinical Trials
Brookes Lawley Building
15 Cotswold Road
Sutton
United Kingdom
SM2 5NG
+44 20 8722 4013
Mark.Webster-Smith@icr.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2004-000168-28

ClinicalTrials.gov (NCT)

NCT00066703

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

Study design

Multicentre randomized interventional treatment trial

Primary study design

Interventional

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?
Results article	results	10/07/2014	09/09/2019	Yes	No
Basic results			09/09/2019	No	No
Plain English results				No	Yes
	Study website				

[Study website](#)

11/11/2025

11/11/2025

No

Yes