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Tamoxifen and Exemestane Trial

Submission date 18/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/06/2010	**Overall study status** Completed	
Last Edited 20/05/2024	**Condition category** Cancer	

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

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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)
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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes