Tamoxifen and Exemestane Trial

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

Study website

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

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2004-000168-28

IRAS number

ClinicalTrials.gov number

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 insitu 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