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A randomised double-blind trial in post-menopausal women with primary breast cancer who have received adjuvant tamoxifen for 2-3 years, comparing subsequent adjuvant exemestane treatment with further tamoxifen

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 19/10/2017	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
960EXE031

Study information

Scientific Title
A randomised double-blind trial in post-menopausal women with primary breast cancer who have received adjuvant tamoxifen for 2-3 years, comparing subsequent adjuvant exemestane treatment with further tamoxifen

Study objectives
Early improvements in disease-free survival have been noted when an aromatase inhibitor is given either instead of or sequentially after tamoxifen in postmenopausal women with oestrogen-receptor-positive early breast cancer. However, little information exists on the long-term effects of aromatase inhibitors after treatment, and whether these early improvements lead to real gains in survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Breast cancer

Interventions
1. Patients in the reference arm will receive an overall course of tamoxifen for 5 years (20 mg /day)

2. Patients in the investigational arm will receive 25 mg/day exemestane (after 2-3 years tamoxifen giving a total of 5 years endocrine therapy)

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Disease-free survival

Secondary outcome measures
Overall survival

Overall study start date
01/01/1998

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. Histologically/cytologically confirmed unilateral operable breast adenocarcinoma
2. Estrogen receptor (ER)+ or ER unknown
3. Adequate therapy for primary disease
4. Postmenopausal
5. Receiving tamoxifen and treated with tamoxifen for 2-3 years
6. Remain free from disease following treatment for primary disease

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
4724

Key exclusion criteria
Not provided at time of registration

Date of first enrolment

01/01/1998

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Weston Park Hospital
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation
Pharmacia Ltd & Upjohn (UK)

Sponsor details
Davy Avenue
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Sponsor type
Industry

Website
http://www.pharmacia.com

ROR
https://ror.org/04x4v8p40

Funder(s)

Funder type

Industry

Funder Name
Pharmacia and Upjohn (UK)

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?
Results article	results of the 2nd interim analysis of efficacy	11/03/2004		Yes	No
Results article	survival and safety results	17/02/2007		Yes	No
Results article	5-year follow-up study results	13/03/2012		Yes	No
Other publications	retrospective analysis	01/04/2012		Yes	No
Results article	long-term follow-up results	01/08/2017		Yes	No