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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr RE Coleman

Contact details

Academic Unit of Clinical Oncology Cancer Research Centre Weston Park Hospital Sheffield United Kingdom S10 2RX +44 (0)114 271 3518 R.E.Coleman@sheffield.ac.uk

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 Milton Keynes United Kingdom MK5 8PH +44 (0)1908 661101 info@adreco.co.uk

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