

# A randomised double-blind trial comparing arimidex alone with nolvadex alone with arimidex and nolvadex in combination, as adjuvant treatment in post-menopausal women with breast cancer

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/04/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-comparing-anastrozole-and-tamoxifen-after-surgery-for-breast-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

ZEN1033IL/29

## **Study information**

### **Scientific Title**

A randomised double-blind trial comparing arimidex alone with nolvadex alone with arimidex and nolvadex in combination, as adjuvant treatment in post-menopausal women with breast cancer

### **Acronym**

ATAC (Arimidex, Tamoxifen, Alone or in Combination)

### **Study objectives**

Not provided at time of registration

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Breast cancer

### **Interventions**

1. Group A: Arimidex (anastrozole) 1 mg plus Nolvadex (tamoxifen) placebo both daily for 5 years or until recurrence
2. Group B: Arimidex 1 mg plus Nolvadex 20 mg, both daily for 5 years or until recurrence
3. Group C: Arimidex placebo plus Nolvadex 20 mg, both daily for 5 years or until recurrence

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/01/1998

**Completion date**

01/12/1999

**Eligibility****Key inclusion criteria**

1. Histologically proven operable breast cancer
2. Patients must have completed primary surgery and chemotherapy (if given), and are candidates to receive hormonal adjuvant therapy
3. Deemed to be post-menopausal according to one of the following:
  - 3.1. Aged >60 years
  - 3.2. Bilateral oophorectomy
  - 3.3. Aged <60 years with a uterus and amenorrhoea for at least 12 months
  - 3.4. Aged <60 without a uterus and with follicle stimulating hormone (FSH) >20IU/L
4. No evidence of metastatic disease
5. If chemotherapy was started more than 8 weeks after primary surgery or chemotherapy was completed more than 8 weeks before randomisation the patients is excluded
6. No neo-adjuvant chemotherapy
7. Surgery must have been completed within 8 weeks prior to randomisation
8. No previous hormonal therapy as adjuvant treatment for breast cancer unless:
  - 8.1. Tamoxifen received prior to first surgical procedure for 28 days or less
  - 8.2. Hormonal therapy received pre-surgery in the context of a formal trial
9. Patients who have received tamoxifen as part of any breast cancer prevention trial are to be excluded
10. No previous malignancy within the last 10 years, except squamous or basal cell carcinoma of the skin or carcinoma in situ of the cervix, adequately cone biopsied
11. No treatment with a non-approved drug during the 3 months before randomisation
12. No medical contraindications to any of the treatments in the trial

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/01/1998

**Date of final enrolment**

01/12/1999

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**ATAC secretariat**

London

United Kingdom

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## **Sponsor information**

**Organisation**

AstraZeneca Clinical Research Group (UK)

**Sponsor details**

10 Logie Mill

Beaverbank Office Park

Lovie Green Road

Edinburgh

United Kingdom

EH7 4HG

**Sponsor type**

Industry

**Website**

<http://www.astrazeneca.co.uk>

**ROR**

<https://ror.org/04r9x1a08>

## Funder(s)

**Funder type**

Industry

**Funder Name**

AstraZeneca Pharmaceuticals (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?
<a href="#">Results article</a>	results	01/01/2005		Yes	No
<a href="#">Results article</a>	results of long-term safety analysis	01/08/2006		Yes	No
<a href="#">Results article</a>	results on 10 year analysis of trial	23/11/2007		Yes	No
<a href="#">Results article</a>	results of 100-month analysis	01/01/2008		Yes	No
<a href="#">Results article</a>	five year results	01/03/2008		Yes	No
<a href="#">Results article</a>	results on the effect of body mass index on recurrence rates	20/07/2010		Yes	No
<a href="#">Results</a>	results				

[article](#)  
[Results](#)  
[article](#)

results

01/12/2010	Yes	No
04/04/2012	Yes	No