

# LATTE: Long-term Anastrozole versus Tamoxifen Treatment Effects

<b>Submission date</b> 19/03/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/04/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Breast cancer is increasingly becoming a “survivable” disease, and an increasing number of recurrences occur late, so that there is much interest about the long-term efficacy and safety of treatments. The Oxford Overview process has provided useful data on follow-up for 15-20 years after tamoxifen therapy. Such data are lacking for the newer aromatase inhibitors (AIs). This study provides a unique opportunity to address this issue. The ‘Arimidex, Tamoxifen, Alone or in Combination’ (ATAC) trial is the vanguard breast cancer trial for the use of AIs in the adjuvant setting, with a median follow-up of 100 months. With the LATTE Study, it is proposed to collect further follow-up information on the 4,300 patients randomised to mono-therapy (anastrozole or tamoxifen). This research will aim to provide additional efficacy (including local and distant recurrence, and new contralateral tumours) data, and information on survival, new primary cancers at other sites, and other major ischaemic cardiac and cerebrovascular events.

### Who can participate?

Women who took part in the ATAC trial in 1996 - 2003.

### What does the study involve?

Study involves collecting long-term follow-up data for patients from the ATAC study (monotherapy arm) on an annual basis. This includes data from routine clinic visits based on local practice, via GP information request and where appropriate, by post or telephone.

### What are the possible benefits and risks of participating?

There are no direct benefits for patients who took part in the ATAC trial, but the data collected through the LATTE study will contribute to better understanding of the effects of both anastrozole and tamoxifen in terms of efficacy and safety in the long term which may benefit patients in the future. There are no risks associated with taking part in the study.

### Where is the study run from?

45 centres in the UK, five in Australia, one in New Zealand, one in Belgium, two in Canada, four in Italy, six in the US, six in France, four in the Netherlands, one in South Africa, 11 in Sweden and three in Germany.

When is the study starting and how long is it expected to run for?  
April 2009 to February 2026. Active data collection from participating hospitals was ongoing until January 2019. After 2019, further long-term follow-up data will be obtained for UK participants only from national registries in the UK (such as NHS Digital), unless the participant withdraws consent to this. All participating hospitals in the UK and other countries have been closed since 2019.

Who is funding the study?  
AstraZeneca

Who is the main contact?  
Professor Jack Cuzick  
j.cuzick@qmul.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Jack Cuzick

**ORCID ID**  
<https://orcid.org/0000-0001-7420-7512>

**Contact details**  
Centre for Cancer Prevention  
Queen Mary University of London  
Wolfson Institute of Preventive Medicine  
Charterhouse Square  
London  
United Kingdom  
EC1M 6BQ  
+44 (0)20 7882 3504  
j.cuzick@qmul.ac.uk

**Type(s)**  
Scientific

**Contact name**  
Miss Joanna Zahedi

**Contact details**  
Project Manager/Data Manager  
Barts CTU  
Centre for Evaluation and Methods  
Wolfson Institute of Population Health  
Faculty of Medicine and Dentistry  
Queen Mary University of London  
London  
United Kingdom

E1 4NS

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j.zahedi@qmul.ac.uk

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT01745289

### Integrated Research Application System (IRAS)

339492

## Study information

### Scientific Title

Long-term Anastrozole versus Tamoxifen Treatment Effects in breast cancer: an epidemiological observational study

### Acronym

LATTE

### Study objectives

The aim of this study is to provide additional efficacy (including local and distant recurrence, and new contralateral tumours) data, and information on survival, new primary cancers at other sites, and other major ischaemic cardiac and cerebrovascular events.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

1. approved 19/01/2009, London – South East (formerly South East Research Ethics Committee) (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8222, (0)207 104 8177, (0)207 104 8263; londonsoutheast.rec@hra.nhs.uk), ref: 09/H1102/1

2. approved 15/02/2024, London - South East Research Ethics Committee (Health Research Authority 2, Redman Place, London , E20 1JQ, United Kingdom; +44 (0)207 104 8222, (0)207 104 8177, (0)207 104 8263; londonsoutheast.rec@hra.nhs.uk), ref: 24/LO/0102

### Study design

International multicentre epidemiological observational study

### Primary study design

Observational

### Study type(s)

Treatment

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

Breast cancer

## Interventions

Current interventions as of 09/04/2024:

There are no trial drugs or treatments associated with this observational study. Long-term follow-up data will be collected for this Research Database for the following outcomes:

Recurrence of breast cancer:

Patients should be reviewed for recurrence of breast cancer at all follow-up visits. The site and date of confirmed first loco-regional and first distant recurrence will be recorded in the follow-up case report form (CRF). After loco-regional and distant recurrence patients will be followed for survival, new primary cancers and subsequent recurrences only. New breast primaries (either contralateral or ipsilateral) will be regarded as disease recurrence events in the statistical analyses of time to recurrence.

Death:

All patients will be followed for survival. Patients will be registered with national digital registries in the UK for longer-term outcome data including death and other outcome data.

New breast primaries:

New breast primaries (either contralateral or ipsilateral), confirmed by histology or cytology, and with no other confirmed recurrence, will be recorded as a new breast primary. Additional information will be requested in order to determine whether the New Breast Primary is invasive or DCIS and whether it is oestrogen-receptor positive.

Other cancers:

New primary cancers confirmed by histology or cytology, or other diagnostic procedure.

Ischaemic cardiac and cerebrovascular events, hip (and other) fractures:

Serious cardiac or cerebrovascular events (such as myocardial infarct or stroke; not angina or transient ischaemic attack), all hip fractures, and fractures leading to an overnight stay in hospital.

Note: From 2019 onwards, follow-up data will continue to be collected solely via national digital registries for UK participants only. Participating sites will no longer collect follow-up data via the aforementioned methods of routine clinic visits, GP information requests, hospital tracking system, telephone contact or postal questionnaire. Participating sites have been closed and will no longer provide this follow-up data to the Barts Clinical Trials Unit.

Previous interventions:

There are no trial drugs or treatments associated with this observational study.

Patients should be reviewed for recurrence of breast cancer at all follow-up visits. The site and date of confirmed first loco-regional and first distant recurrence will be recorded in the follow-up case report form (CRF). After loco-regional and distant recurrence patients will be followed for survival, new primary cancers and subsequent recurrences only. New breast primaries (either contralateral or ipsilateral) will be regarded as disease recurrence events in the statistical analyses of time to recurrence.

All patients will be followed for survival. Patients will be registered with national death registries, where possible, e.g. ONS in UK. Cause of death will be recorded.

### New breast primaries:

New breast primaries (either contralateral or ipsilateral), confirmed by histology or cytology, and with no other confirmed recurrence, will be recorded as a new breast primary. Additional information will be requested in order to determine whether the New Breast Primary is invasive or DCIS and whether it is oestrogen-receptor positive.

### Other cancers:

New primary cancers confirmed by histology or cytology, or other diagnostic procedure.

### Ischaemic cardiac and cerebrovascular events, hip (and other) fractures:

Serious cardiac or cerebrovascular events (such as myocardial infarct or stroke; not angina or transient ischaemic attack), all hip fractures, and fractures leading to an overnight stay in hospital.

## Intervention Type

Other

## Primary outcome(s)

Time to recurrence of breast cancer in the post 10 year period (defined as the earliest of local or distant recurrence, new primary breast cancer, or death).

## Key secondary outcome(s)

To compare the long-term effects of tamoxifen (20 mg once daily [od]) and anastrozole (1 mg od) which were given in the ATAC trial (and who have all now completed treatment) as adjuvant therapy in terms of:

1. Time to distant recurrence
2. Cancer-specific survival
3. New breast primaries
4. Other cancers
5. Ischaemic cardiac and cerebrovascular events
6. Hip (and other) fractures

## Completion date

28/02/2026

# Eligibility

## Key inclusion criteria

1. Patients randomised to one of the monotherapy arms in the ATAC trial (randomised to the ATAC trial during the period 1996 - 2003 and were female, post-menopausal and 45 years and above at the time of randomisation)
2. Alive at 10 years follow-up

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

**Lower age limit**

45 years

**Sex**

Female

**Total final enrolment**

1342

**Key exclusion criteria**

1. Patients who have withdrawn consent to participate in the ATAC trial or this study
2. Where the LATTE Executive Committee determines that there is no possibility of obtaining follow-up

**Date of first enrolment**

11/03/2010

**Date of final enrolment**

21/01/2019

## **Locations**

**Countries of recruitment**

United Kingdom

England

Australia

Belgium

Canada

France

Germany

Italy

Netherlands

New Zealand

South Africa

Sweden

United States of America

**Study participating centre**  
**Centre for Cancer Prevention**  
327 Mile End Road  
London  
United Kingdom  
E1 4NS

## Sponsor information

**Organisation**  
Queen Mary University of London (UK)

**ROR**  
<https://ror.org/026zzn846>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Cancer Research UK (CRUK) (UK) (ref: C569/A10400)

**Alternative Name(s)**  
CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

**Funder Name**  
AstraZeneca (UK)

**Alternative Name(s)**  
AstraZeneca PLC, Pearl Therapeutics, AZ

## Funding Body Type

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. An application process is in place for researchers wishing to use the LATTE data outside of those specified in the study protocol. In brief, a proposal for new analysis is formally assessed via the submission of a Request for New Analysis (RNA) form to the LATTE Executive and Advisory Committees.

## IPD sharing plan summary

Stored in non-publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	10-year follow-up results	01/12/2010	25/02/2019	Yes	No
<a href="#">Results article</a>	results	01/11/2003	25/02/2019	Yes	No
<a href="#">Results article</a>	results	01/01/2008	25/02/2019	Yes	No
<a href="#">Abstract results</a>	100-month follow-up conference abstract	01/02/2017	25/02/2019	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes