ISRCTN86305500 https://doi.org/10.1186/ISRCTN86305500

LATTE: Long-term Anastrozole versus Tamoxifen Treatment Effects

Submission date 19/03/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 30/03/2009	**Overall study status** Ongoing	[_] Statistical analysis plan [X] Results
Last Edited 24/04/2025	**Condition category** Cancer	[_] 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 is 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

Study website
https://www.qmul.ac.uk/wolfson/research-projects/current-projects/projects/latte-study.html

Contact information

Type(s)
Scientific

Contact name
Prof Jack Cuzick

ORCID ID
http://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
-
j.zahedi@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
339492

ClinicalTrials.gov number
NCT01745289

Secondary identifying numbers
IRAS 339492

Study information

Scientific Title
Long-term Anastrozole versus Tamoxifen Treatment Effects in breast cancer: an epidemiologial 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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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).

Secondary outcome measures
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

Overall study start date

01/04/2009

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

Age group
Adult

Lower age limit
45 Years

Sex
Female

Target number of participants
4437 participants internationally were eligible for further long-term follow-up in the LATTE study

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
Australia

Belgium

Canada

England

France

Germany

Italy

Netherlands

New Zealand

South Africa

Sweden

United Kingdom

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)

Sponsor details
The Joint Research Management Office
Queen Mary Innovation Centre
Lower Ground Floor
5 Walden Street
London
England
United Kingdom
E1 2EF
+44 (0)20 7882 7260
research.governance@qmul.ac.uk

Sponsor type
University/education

Website
http://www.jrmo.org.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, 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

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 09/04/2024:
The intention is to publish the main results from the study in approximately 2026 (when median follow-up reaches 15 years) in a high-impact peer-reviewed journal. Following this, the aim is to publish an updated manuscript on the benefits of aromatase inhibitors (AI) therapy in 2026/2027.

Previous publication and dissemination plan:
The intention is to publish the main results from the study in 2018 in a high-impact peer-reviewed journal. Following this, the aim is to publish an updated manuscript on the benefits of aromatase inhibitors (AI) therapy in 2022/2023.

Intention to publish date

31/12/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically 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?
Abstract results	100-month follow-up conference abstract	01/02/2017	25/02/2019	No	No
Results article	10-year follow-up results	01/12/2010	25/02/2019	Yes	No
Results article	results	01/11/2003	25/02/2019	Yes	No
Results article	results	01/01/2008	25/02/2019	Yes	No