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LOTUS: LOng-Term follow-Up Study of triple-negative breast cancer

Submission date 12/05/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 30/05/2014	**Overall study status** Completed	
Last Edited 30/06/2025	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-the-long-term-outcomes-and-impact-of-treatment-for-triple-negative-breast-cancer-lotus

Study website
http://ctru.leeds.ac.uk/lotus

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An international multi-centre long-term follow-up study of the long-term outcomes and impact of cancer treatments in 'triple-negative' breast cancer

Acronym
LOTUS

Study objectives
The LOTUS study aims to collect valuable information on the long-term effects and the impact of cancer treatments for patients with triple-negative breast cancer (TNBC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West – Central Bristol, 21/11/2014, REC ref: 14/SW/1163, IRAS project ID: 158206

Study design
International observational non-CTIMP long-term follow-up study

Primary study design
Observational

Secondary study design
Cohort study

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
Triple-negative breast cancer

Interventions
No medicinal products (investigational or non-investigational) are being administered as part of this protocol.

Ten years after the participant entered the BEATRICE trial, a hospital visit will take place which will include measuring blood pressure and a heart scan to test heart function.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Avastin

Primary outcome measure
1. The rate of disease-free survival at 10 years post-randomisation to the BEATRICE trial
2. The point prevalence of severe cardiac events at 10 years post-randomisation to the BEATRICE trial

Secondary outcome measures
Breast cancer endpoints:
1. Overall survival and cause of death at 10 years post-BEATRICE randomisation
2. Invasive disease-free survival at 10 years post-BEATRICE randomisation
3. Distant disease-free survival at 10 years post-BEATRICE randomisation
4. Overall survival and cause of death at 15 years post-BEATRICE randomisation

Cardiovascular endpoints:
1. The point prevalence by severity of cardiac morbidity, vascular events, cardiovascular risk factors and thyroid dysfunction at 10 years post-BEATRICE randomisation
2. The cumulative incidence of cardiac morbidity, vascular events, cardiovascular risk factors and thyroid dysfunction between entry into LOTUS and 10 years post-BEATRICE randomisation

Other endpoints:
1. The cumulative incidence of secondary primary malignancies at 10 years post-BEATRICE randomisation
2. The cumulative incidence of myelodysplasia at 10 years post-BEATRICE randomisation
3. The cumulative incidence of osteoporosis at 10 years post-BEATRICE randomisation
4. The cumulative incidence of reproductive health issues at 10 years post-BEATRICE randomisation

Overall study start date
01/07/2014

Completion date
01/04/2025

Eligibility

Key inclusion criteria

1. Participated in the BEATRICE trial
2. Aged 18 or over
3. Currently being followed up at a site participating in the LOTUS study
4. Able to provide informed consent and comply with the trial schedule

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Approximately 250-500 participants

Total final enrolment
226

Key exclusion criteria
1. Withdrawn from follow up from the BEATRICE trial
2. Given adjuvant endocrine therapy after completion of adjuvant chemotherapy

Date of first enrolment
30/10/2014

Date of final enrolment
03/01/2017

Locations

Countries of recruitment
Australia

Austria

Brazil

Canada

England

France

Germany

Hong Kong

Israel

Italy

Japan

Korea, South

New Zealand

Philippines

Poland

Spain

Taiwan

Thailand

United Kingdom

Study participating centre
Leeds Institute of Clinical Research
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Medicine and Health Faculty Office
University of Leeds
Leeds
England
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Sponsor type
University/education

ROR

https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
F. Hoffman-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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?
HRA research summary			28/06/2023	No	No