

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

<b>Submission date</b> 12/05/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/05/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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>

## Contact information

### Type(s)

Scientific

### Contact name

Prof David Cameron

### Contact details

c/o Clinical Trials Research Unit  
Leeds Institute of Clinical Research  
Leeds  
United Kingdom  
LS2 9JT  
-  
lotus@leeds.ac.uk

## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

Australia

Austria

Brazil

Canada

France

Germany

Hong Kong

Israel

Italy

Japan

Korea, South

New Zealand

Philippines

Poland

Spain

Taiwan

Thailand

**Study participating centre**

Leeds Institute of Clinical Research

Leeds

United Kingdom  
LS2 9JT

## Sponsor information

### Organisation

University of Leeds (UK)

### ROR

<https://ror.org/024mrx33>

## 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

### 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="#">HRA research summary</a>			28/06/2023	No	No

[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes