

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

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

## Study website

<http://ctr.leeds.ac.uk/lotus>

## Contact information

### Type(s)

Scientific

### Contact name

Prof David Cameron

### Contact details

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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  
United Kingdom  
LS2 9JT

**Sponsor type**  
University/education

**ROR**

## 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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |