

# PRIMETIME – Post-operative avoidance of radiotherapy in minimal risk women: patient selection using biomarkers

<b>Submission date</b> 30/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/03/2017	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/11/2025	<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

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/study-radiotherapy-women-small-risk-breast-cancer-returning-primetime>

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

190307

**ClinicalTrials.gov (NCT)**

Nil known

**Central Portfolio Management System (CPMS)**

CPMS 33217

## **Study information**

### **Scientific Title**

Post-operative avoidance of radiotherapy: biomarker selection of women categorised to be in a very low risk group by IHC4+C

### **Acronym**

PRIMETIME

### **Study objectives**

The aim of this study is to test whether radiotherapy can be safely avoided in a patient population considered to have such a low risk of local recurrence that the potential absolute gain from radiotherapy is so small as to not outweigh the established risks associated with breast radiotherapy.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

East of England – Cambridgeshire and Hertfordshire Research Ethics Committee, 05/09/2016, ref: 16/EE/0305

### **Study design**

Non-randomized; Interventional; Design type: Treatment, Radiotherapy, Management of Care

### **Primary study design**

Intentional

### **Study type(s)**

Treatment

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

Breast cancer

### **Interventions**

Patients consent and register for pre-screening Ki67 research testing and 5 slides from the diagnostic block are forwarded for analysis to the central laboratory. Breast conserving surgery will proceed according to standard practice. If a patient is confirmed as eligible (meets inclusion and exclusion criteria) they will then be consented for the main PRIMETIME study. The IHC4+C calculator is then utilised to direct treatment according to the patient's risk category (i.e. if they are deemed 'very low risk' they will be recommended to avoid radiotherapy). All patients will then receive either standard breast radiotherapy or no radiotherapy and standard adjuvant hormone therapy and any additional anti-cancer treatments.

For patients who receive radiotherapy they will have 5 years of annual mammograms, for patients who do not receive radiotherapy they will be required to attend for 10 years of annual mammograms. Patients will be followed up for 10 years in clinic and thereafter via routine data sources.

Added 27/11/2025:

Additional Data Linkage Information:

Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website: <https://www.icr.ac.uk/interact>.

## **Intervention Type**

Other

## **Primary outcome(s)**

Ipsilateral breast local relapse rate 5 years from study registration is assessed through patient note review.

## **Key secondary outcome(s)**

1. Ipsilateral breast local relapse rate is measured by patient note review 10 years from study registration
2. Regional relapse rate is measured by patient note review at 5 and 10 years
3. Distant relapse rate is measured by patient note review at 5 and 10 years
4. Overall survival is measured by patient note review at 5 and 10 years
5. Breast cancer specific survival is measured by patient note review at 5 and 10 years

## **Completion date**

19/05/2030

## **Eligibility**

### **Key inclusion criteria**

1. Provision of written informed consent to participate in the PRIMETIME study
2. Provision of slides for research testing and availability of KI67 result (contact ICR-CTSU to confirm)
3. Women aged  $\geq 60$  years (younger patients are eligible if they are post-menopausal and have comorbidities that imply a high risk of radiotherapy toxicity e.g. significant cardiovascular disease with left sided breast cancer)
4. Women having had breast conserving surgery with complete resection of tumour tissue ( $\geq 1$  mm microscopic, circumferential margins of normal tissue from invasive cancer and DCIS)
5. AJCC staging of pT1/pN0/M0 (DCIS is allowed in combination with invasive breast cancer; isolated tumour cells in axillary nodes are allowed)
6. Histological confirmation of grade 1 or 2 invasive breast cancer
7. Oestrogen receptor (ER) positive according to local practice. The H score must be available.
8. Progesterone receptor (PR) positive according to local practice. The percentage positivity must be available.
9. Human epidermal growth factor receptor (HER2) negative according to local practice
10. Patients must be recommended for  $\geq 5$  years adjuvant endocrine therapy according to local policy and in the investigator's opinion, deemed able to comply with the duration of treatment

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

0

**Key exclusion criteria**

1. Patients known to have lymphovascular space invasion and/or axillary nodal micrometastases or macrometastases.
2. Patients with a past history of malignancy except:
  - 2.1. Basal cell skin cancer and CIN cervix uteri
  - 2.2. Treated, localised squamous cell carcinoma of the skin
  - 2.3. Malignancies treated with curative intent and the patient has been disease free  $\geq 5$  years
3. Patients who have had an ipsilateral mastectomy
4. Patients who have received neoadjuvant therapy (endocrine or cytotoxic chemotherapy with therapeutic intent) or who are deemed by the MDT to require adjuvant cytotoxic chemotherapy
5. Patients with mammographically occult breast cancers, ie. present with lump, but not visible on mammogram

**Date of first enrolment**

17/03/2017

**Date of final enrolment**

28/02/2022

## **Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

Wales

**Study participating centre**

**Addenbrookes Hospital**

Hills Road

Cambridge  
England  
CB2 0QQ

**Study participating centre**

**Raigmore Hospital**

Old Perth Road  
Inverness  
Scotland  
IV2 3UJ

**Study participating centre**

**Wrexham Maelor**

Cresnewydd Road  
Wrexham  
Wales  
LL13 7TD

**Study participating centre**

**Norfolk and Norwich University Hospital**

Colney Lane  
Norwich  
England  
NR4 7UY

**Study participating centre**

**Barts Hospital**

W Smithfield  
London  
England  
EC1A 7BE

**Study participating centre**

**Royal Free Hospital**

Pond Street  
London  
England  
NW3 2QG

**Study participating centre**  
**Mount Vernon Hospital**  
Rickmansworth Road  
Northwood  
England  
HA6 2RN

**Study participating centre**  
**Lister Hospital**  
Coreys Mill Lane,  
Stevenage  
England  
SG1 4AB

**Study participating centre**  
**Queen Elizabeth II Hospital**  
Howlands  
Welwyn Garden City  
England  
AL7 4HQ

**Study participating centre**  
**Charing Cross Hospital**  
Fulham Palace Road  
London  
England  
W6 8RF

**Study participating centre**  
**University Hospital of South Manchester**  
Southmoor Road,  
Wythenshawe  
Manchester  
England  
M23 9LT

**Study participating centre**  
**Churchill Hospital**  
Old Road,  
Headington  
Oxford

England  
OX3 7LE

**Study participating centre**  
**The Hillingdon Hospital**  
Pield Heath Road  
Uxbridge  
England  
UB8 3NN

**Study participating centre**  
**Clatterbridge Cancer Centre**  
Clatterbridge Health Park,  
Clatterbridge Road,  
Birkenhead  
Wirral  
England  
CH63 4JY

**Study participating centre**  
**The Royal Marsden**  
203 Fulham Road  
London  
England  
SW3 6JJ

**Study participating centre**  
**The Royal Marsden**  
Downs Road  
Sutton  
England  
SM2 5PT

**Study participating centre**  
**The Royal Bournemouth Hospital**  
Castle Lane East  
Bournemouth  
England  
BH7 7DW

**Study participating centre**  
**Royal Glamorgan Hospital**  
Ynysmaerdy  
Llantrisant  
Wales  
CF72 8XR

**Study participating centre**  
**Musgrove Park Hospital**  
Parkfield Drive  
Taunton  
England  
TA1 5DA

**Study participating centre**  
**West Suffolk Hospital**  
Hardwick Lane  
Bury Saint Edmunds  
England  
IP33 2QZ

## **Sponsor information**

**Organisation**  
Institute of Cancer Research

**ROR**  
<https://ror.org/043jzw605>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Cancer Research UK

**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

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Interim results article</a>		14/06/2021	13/08/2021	Yes	No
<a href="#">Protocol file</a>	version v3.0	03/05/2019	16/03/2021	No	No
<a href="#">Protocol file</a>	version 4.0	13/01/2021	07/11/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes