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

Submission date 30/01/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/03/2017	**Overall study status** Ongoing	
Last Edited 07/11/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/study-radiotherapy-women-small-risk-breast-cancer-returning-primetime

Study website
https://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/clinical-trials/primetime

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
190307

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 33217, IRAS 190307

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
Interventional

Secondary study design
Non randomised 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
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.

Intervention Type
Other

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

Secondary outcome measures
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 reviewat 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

Overall study start date
01/07/2015

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 ≥60 years (younger patients are eligible if they are post-menopausal and have co-morbidities 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 (≥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 ≥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

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 2400; UK Sample Size: 2400

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 excep:
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 ≥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
England

Scotland

United Kingdom

Wales

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Raigmore Hospital
Old Perth Road
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Wrexham Maelor
Cresnewydd Road
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Barts Hospital
W Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Royal Free Hospital
Pond Street

London
United Kingdom
NW3 2QG

Study participating centre
Mount Vernon Hospital
Rickmansworth Road
Northwood
United Kingdom
HA6 2RN

Study participating centre
Lister Hospital
Coreys Mill Lane,
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Queen Elizabeth II Hospital
Howlands
Welwyn Garden City
United Kingdom
AL7 4HQ

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
University Hospital of South Manchester
Southmoor Road,
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Churchill Hospital
Old Road,
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
The Hillingdon Hospital
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
Clatterbridge Cancer Centre
Clatterbridge Health Park,
Clatterbridge Road,
Birkenhead
Wirral
United Kingdom
CH63 4JY

Study participating centre
The Royal Marsden
203 Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
The Royal Marsden
Downs Road
Sutton
United Kingdom
SM2 5PT

Study participating centre

The Royal Bournemouth Hospital
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Royal Glamorgan Hospital
Ynysmaerdy
Llantrisant
United Kingdom
CF72 8XR

Study participating centre
Musgrove Park Hospital
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
West Suffolk Hospital
Hardwick Lane
Bury Saint Edmunds
United Kingdom
IP33 2QZ

Sponsor information

Organisation
Institute of Cancer Research

Sponsor details
Royal Cancer Hospital
237 Fulham Road
London
United Kingdom
SW3 6JB

Sponsor type
Research organisation

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
19/05/2031

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

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?
Protocol file	version v3.0	03/05/2019	16/03/2021	No	No
Interim results article		14/06/2021	13/08/2021	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	13/01/2021	07/11/2023	No	No