

# National randomised trial of hormone replacement therapy (HRT) in women with a history of early stage breast cancer

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-hormone-replacement-therapy-for-women-who-have-had-treatment-for-breast-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

Ms Lisa Lloyd

### Contact details

Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)  
Section of Epidemiology  
Brookes Lawley Building  
Cotswold Road  
Sutton, Surrey  
United Kingdom  
SM2 5NG  
+44 (0)208 722 4063  
[lisa.lloyd@icr.ac.uk](mailto:lisa.lloyd@icr.ac.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00079248

**Secondary identifying numbers**

N/A

## Study information

**Scientific Title**

National randomised trial of hormone replacement therapy (HRT) in women with a history of early stage breast cancer

**Acronym**

HRT

**Study objectives**

Not provided at time of registration

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

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

Breast

**Interventions**

1. HRT
2. No HRT (advice about non-hormonal alternatives)

Trial was closed early (December 2005) due to poor recruitment.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/08/2003

**Completion date**

01/08/2006

**Reason abandoned (if study stopped)**

Participant recruitment issues

## Eligibility

**Key inclusion criteria**

1. Patients must have had proven stage I/II breast cancer with no clinical evidence of recurrence since diagnosis
2. Have been given a patient information pack
3. Be postmenopausal as defined by:
  - a. Having been amenorrhoeic for at least 6 months (including women who have had radiation or chemical induced ovarian suppression) irrespective of menopausal status at time of diagnosis
  - b. Having received surgical bilateral oophorectomy
  - c. Be experiencing vasomotor symptoms (i.e. hot flushes or night sweats) with or without vaginal dryness.

All such women are eligible irrespective of current/previous treatment for breast cancer.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Female

**Target number of participants**

Modified 25/02/2010: 3000

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/08/2003

**Date of final enrolment**

01/08/2006

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)**

Sutton, Surrey

United Kingdom

SM2 5NG

## **Sponsor information**

**Organisation**

Individual Sponsor (UK)

**Sponsor details**

C/o Mr Nigel Sacks

The Royal Marsden NHS Trust

London

United Kingdom

SM2 5NG

+44 (0) 20 8722 4373

Claire.Dawson@icr.ac.uk

**Sponsor type**

Research organisation

**Website**

<http://www.cancer.org.uk>

## **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**

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