

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

Submission date 01/07/2001	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2001	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/01/2019	Condition category 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

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00079248

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

United Kingdom

England

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)

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