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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	[X] Prospectively registered [_] Protocol
Registration date 01/07/2001	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 28/01/2019	**Condition category** Cancer	[_] Individual participant data [_] 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

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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
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Sponsor information

Organisation
Individual Sponsor (UK)

Sponsor details
C/o Mr Nigel Sacks
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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