ISRCTN29941643 https://doi.org/10.1186/ISRCTN29941643

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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/07/2001	**Overall study status** Stopped	
Last Edited 28/01/2019	**Condition category** Cancer	

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

Protocol serial number
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

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