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The PRIME Breast Cancer Trial: Postoperative Radiotherapy in Minimum-Risk Elderly

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 17/10/2018	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/radiotherapy-after-surgery-for-breast-cancer-for-women-over-65-years-old

Study website
http://homepages.ed.ac.uk/prime/prime.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 96/03/01

Study information

Scientific Title
The PRIME Breast Cancer Trial: Postoperative Radiotherapy in Minimum-Risk Elderly

Acronym
PRIME I

Study objectives
To assess whether the omission of post-operative radiotherapy in women with low risk axillary node negative breast cancer (T0-2) treated by breast conservation with wide local excision and endocrine therapy:
1. Improves quality of life
2. Is more cost-effective

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 23/08/2007: Multicentre Research Ethics Committee (MREC) approval was granted by the Scotland Committee on 15 October 1998.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions

Please note that, as of 10 January 2008, the anticipated start and end dates of this trial have been updated from 1 September 1999 and 31 December 2003 to 1 January 1999 and 30 November 2005, respectively.

Interventions:
Patients treated by conservation surgery and adjuvant endocrine therapy will be randomised to receive or not to receive breast irradiation

See details of PRIME II trial on http://www.controlled-trials.com/ISRCTN95889329

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Quality of life assessed by:
i. EORTC QLQ-C30 and QLQ-BR23
ii. Philadelphia Geriatric Center Morale Scale
iii. EuroQol
2. Anxiety and depression assessed by the Hospital Anxiety and Depression Scale
3. Cost-effectiveness

Secondary outcome measures
1. Loco-regional and distant recurrence rate
2. Functional status assessed by Clackmannan and Barthel scales
3. Acute and late morbidity assessed by the RTOG/EORTC SOMA scale
4. Cosmesis assessed by the Harris scale and the Van Limbergen scale

Overall study start date
01/01/1999

Completion date
30/11/2005

Eligibility

Key inclusion criteria
1. Age of 65 years or more, receiving adjuvant endocrine therapy
2. Medically suitable to attend for all treatments and follow ups
3. Histologically confirmed unilateral breast cancer of Tumour, Metastasis, Node (TMN) stages T0-2
4. No axillary node involvement on histological assessment
5. Had breast conserving surgery with complete excision on histological assessment
6. Able and willing to give informed consent

Participant type(s)

Patient

Age group
Senior

Sex
Female

Target number of participants
255 randomised, additional 100 in parallel self-selected cohort

Key exclusion criteria
1. Past history of pure in situ carcinoma of either breast or previous or concurrent malignancy within the past five years other than non-melanomatous skin cancer or carcinoma in situ of cervix
2. Grade III cancer with lymphatic/vascular invasion (because of higher risk of local recurrence)

Date of first enrolment
01/01/1999

Date of final enrolment
30/11/2005

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
PRIME Administrator
Edinburgh
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	01/08/2007		Yes	No