

Post-operative Radiotherapy In Minimum-risk Elderly - Phase II

| | | |
|--|---|---|
| Submission date 17/06/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 17/08/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 16/02/2023 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-radiotherapy-after-surgery-for-women-with-breast-cancer-over-65-years-old>

Contact information

Type(s)

Scientific

Contact name

Dr Ian Kunkler

Contact details

Edinburgh Cancer Centre
Western General Hospital
Crewe Road
Edinburgh
United Kingdom
EH4 2XU
+44 (0)131 537 2214
i.kunkler@ed.ac.uk

Additional identifiers

Protocol serial number

CZH/4/296

Study information

Scientific Title

Post-operative Radiotherapy In Minimum-risk Elderly - Phase II

Acronym

PRIME II

Study objectives

To assess the role of post-operative breast radiotherapy in women aged 65 or older, with low risk breast cancer treated by breast conserving surgery and adjuvant endocrine therapy: in particular to estimate the difference in local recurrence rates between patients treated with and without radiotherapy.

This trial is related to PRIME I and details in <http://www.controlled-trials.com/ISRCTN14817328>

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 cancer

Interventions

The control arm receive standard breast irradiation (40-50 Gy) over 3-6 weeks and the experimental group receive no breast irradiation. All eligible patients are to receive some form of endocrine therapy.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Ipsilateral breast cancer recurrence rates

Key secondary outcome(s))

Regional recurrence, contralateral breast cancer, distant metastases, disease free survival and overall survival

Completion date

30/11/2008

Eligibility

Key inclusion criteria

1. Breast conserving surgery with a complete pathological excision margin of all invasive and non invasive cancer (a minimum of 1 mm on histological assessment)
2. Histologically confirmed unilateral breast cancer of pathological size 3 cm or less
3. Oestrogen receptor or progesterone receptor positive and treated with post-operative adjuvant endocrine therapy (patients who have been treated with pre-operative neo-adjuvant endocrine therapy can be included)
4. No axillary node involvement on histological assessment
5. Medically suitable to attend for all treatment and follow up
6. Able and willing to give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

Female

Total final enrolment

1326

Key exclusion criteria

1. Age younger than 65 years (date of issue of pathology results)
2. Grade III cancer combined with lymphatic/vascular invasion
3. Previous in situ or invasive carcinoma of either breast
4. Current or previous malignancy, within the past 5 years, other than non-melanomatous skin cancer or carcinoma in situ of cervix

Date of first enrolment

01/01/2003

Date of final enrolment

30/11/2008

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
Edinburgh Cancer Centre
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
University of Edinburgh (UK)

ROR
<https://ror.org/01nrxf90>

Funder(s)

Funder type
Charity

Funder Name
Robertson Trust, Glasgow. Trial was allowed to use unspent funds from another trial to set up the initial stages of the trial.

Funder Name
Chief Scientist Office, Scottish Executive (ref CZH/4/296)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/03/2015 | | Yes | No |
| Results article | | 16/02/2023 | 16/02/2023 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |

[Plain English results](#)

No

Yes