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

Submission date 17/06/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/08/2005	**Overall study status** Completed	
Last Edited 16/02/2023	**Condition category** Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
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 measure
Ipsilateral breast cancer recurrence rates

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

Overall study start date
01/01/2003

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

Age group
Senior

Sex
Female

Target number of participants
1000

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
Scotland

United Kingdom

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

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
Old College
South Bridge
Edinburgh
Scotland
United Kingdom
EH8 9YL
+44 (0)131 650 1000
communications.office@ed.ac.uk

Sponsor type
University/education

Website
http://www.ed.ac.uk/

ROR
https://ror.org/01nrxwf90

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results				No	Yes
Results article	results	01/03/2015		Yes	No
Results article		16/02/2023	16/02/2023	Yes	No