

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

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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

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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/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

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