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3D conformal Radiation therapy for Accelerated Partial breast IrraDiation (RAPID) trial

Submission date	Recruitment status	[_] Prospectively registered
24/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/06/2022	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00282035

Secondary identifying numbers
MCT-78567

Study information

Scientific Title
3D conformal Radiation therapy for Accelerated Partial breast IrraDiation (RAPID) trial

Acronym
RAPID

Study objectives
Accelerated partial breast irradiation (APBI) is equivalent to whole breast irradiation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of McMaster University, 23/12/2005, ref: 05-440. McMaster REB approved protocol amendment 1 with a revised ICF on 20/05/2008.

Study design
Multicentre two-arm non-inferiority randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
1. Control arm: whole breast irradiation
2. Experimental arm: accelerated partial breast irradiation using 3D conformal therapy

Intervention Type
Procedure/Surgery

Primary outcome measure

Timepoints added 18/11/2008:
Ipsilateral breast or axillary recurrence, measured at any point throughout the trial.

Secondary outcome measures
Timepoints added 18/11/2008:
1. Cosmetic outcome, measured at 1, 3, 5 and 10 years
2. Radiation toxicity, acute at 2 weeks post radiation, late at 1, 3, 5, 10 years
3. Disease free survival, measured time from randomisation to time of documented recurrent disease
4. Event free survival, measured from time from randomisation to time of documented cancer or death
5. Overall survival, measured from time from randomisation to death
6. Quality of life, measured at 1, 3, 5, 10 years
7. Cost effectiveness, measured from a sample of 20% of trial population (treatment resources)

Overall study start date
01/01/2006

Completion date
31/01/2014

Eligibility

Key inclusion criteria
Modifications as of 18/11/2008: point three of the inclusion criteria has been updated as follows:
3. Negative axillary node involvement including micrometastasis less than or equal to 0.2 mm or positive cells only identified by immunohistochemistry (IHC) as determined by:
3.1. Sentinel node biopsy
3.2. Axillary node dissection
3.3. Clinical exam for patients with DCIS only

Initial information at time of registration:
1. Female patients, 40 years and older, with a new histological diagnosis of ductal carcinoma in situ (DCIS) or invasive carcinoma of the breast with no evidence of metastatic disease
2. Treated by breast-conserving surgery (BCS) with microscopically clear resection margins (or no residual disease on re-excision) and considered a candidate for breast irradiation
3. Negative axillary node involvement determined by sentinel node biopsy, axillary node dissection or clinical exam in women greater than 70 years of age

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
2128

Key exclusion criteria
Modifications as of 18/11/2008: the exclusion criteria have been updated as follows:
1. Aged less than 40 years
2. A known deleterious mutation in BRCA 1 and/or BRCA 2
3. Tumour size greater than 3 cm in greatest diameter on pathological examination (including both invasive and non-invasive components)
4. Tumour histology limited to lobular carcinoma only
5. Bilateral invasive or non-invasive malignancy of the breast (synchronous or metachronous)
6. More than one primary tumour in different quadrants of the same breast
7. Previous irradiation to the ipsilateral breast that would preclude WBI
8. Presence of an ipsilateral breast implant or pacemaker
9. Serious non-malignant disease (e.g. cardiovascular, pulmonary, systemic lupus erythematosus (SLE), scleroderma) which would preclude definitive radiation treatment
10. Oestrogen receptor status (ER) not known
11. For patients not treated with adjuvant chemotherapy: unable to commence radiation therapy within 12 weeks of the last surgical procedure on the breast
12. For patients treated with adjuvant chemotherapy: unable to commence within 8 weeks of the last dose of chemotherapy
13. History of cancer:
13.1. Patients with another active malignancy or malignancy treated less than 5 years prior to randomisation are excluded with the exception of prior non-invasive contralateral breast cancer
13.2. Patients with a prior diagnosis of invasive breast cancer in either breast are excluded regardless of disease free interval
13.3. Patients with prior or concurrent basal cell or squamous cell skin cancers are eligible for the trial
14. Currently pregnant or lactating
15. Psychiatric or addictive disorders which would preclude obtaining informed consent or adherence to protocol
16. Geographic inaccessibility for follow-up
17. Inability to localise surgical cavity on CT (i.e., no evidence of surgical clips or seroma)
18. Inability to adequately plan the patient for the experimental technique. The Dose Evaluation Volume (DEV) should be less than or equal to 25% of the total breast volume, or less than or equal to 35% whilst meeting other criteria mentioned in full in the protocol.

Initial information at time of registration:
1. Any patient with known breast cancer genes (BRCA 1 or 2)
2. Aged less than 40 years
3. Tumour greater than 3 cm in greatest diameter on pathological examination
4. Tumour histology involving lobular carcinoma
5. Inability to localise surgical cavity on computed tomography (CT) (i.e., no evidence of surgical clips or seroma)
6. Inability to adequately plan the patient for the experimental technique; seroma should be less than 25% of the total breast volume
7. Bilateral invasive malignancy of the breast (synchronous or metachronous)
8. More than one primary tumour in different quadrants of the same breast
9. Previous or concomitant malignancies except non-melanoma skin cancer, carcinoma in situ of

the cervix, contralateral non-invasive breast cancer, and invasive carcinomas of cervix, endometrium, colon, and thyroid treated 5 years prior to study entry
10. Currently pregnant or lactating
11. Serious non-malignant disease (e.g. cardiovascular, pulmonary, systemic lupus erythematosus [SLE], scleroderma) which preclude definitive radiation treatment
12. Psychiatric or addictive disorders which would preclude obtaining informed consent or adherence to protocol
13. Geographic inaccessibility for follow-up
14. Status for adjuvant systemic therapy not determined
15. Unable to commence radiation within 12 weeks of the last surgical procedure on the breast where the patient is not treated with adjuvant chemotherapy, or unable to commence within 8 weeks of the last dose of chemotherapy where the patient is treated with adjuvant chemotherapy

Date of first enrolment
01/01/2006

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
Canada

Study participating centre
Juravinski Cancer Centre
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Sponsor information

Organisation
McMaster University (Canada)

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Sponsor type
University/education

Website

http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-78567)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Interim results article	interim results	10/11/2013	14/02/2019	Yes	No
Results article		14/12/2019	08/06/2022	Yes	No