

Randomised trial comparing conventional versus short-course reduced volume conformal post-surgery radiation treatment in women with stage I or II Breast cancer

Submission date 10/04/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 13/04/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/05/2013	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

2007/009

Study information

Scientific Title

Acronym

TomoBreast

Study objectives

To test that short course adjuvant radiotherapy with the Tomotherapy system will substantially reduce the incidence of pulmonary and cardiac toxicities, as compared with conventional radiotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Medical Ethics Committee of the UZ Brussel on the 29th March 2007 (ref: 2007/009; B.U.N. ref: B14320071552).

Study design

Randomised, controlled, single centre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Patients eligible for adjuvant post-surgery radiotherapy are randomised between treatment by conventional radiotherapy (control arm) and treatment with Tomotherapy (experimental arm).

Arm I (control, conventional radiotherapy):

Radiotherapy using tangential chest fields, and supraclavicular field in case of nodal involvement, according to our hospital's standard procedure.

Dose-fractionation: 50 Gy in 25 fractions over five weeks, 2 Gy/fraction. Additional boost 16 Gy in 8 fractions over two weeks if breast conserving surgery and aged less than or equal to 70 years.

Arm II (experimental) radiotherapy using the Tomotherapy system:

Target area (breast, thorax wall, nodal areas) delimited according to pre-operative imaging and pathological description.

Dose-fractionation: 42 Gy in 15 fractions over 3 weeks, 2.8 Gy/fraction. Simultaneous boost 0.6 Gy/fraction if breast conserving surgery.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Pulmonary and cardiac toxicities: this will be assessed by respiratory and heart function tests at one to three months after completion of radiotherapy then yearly for three years.

Key secondary outcome(s)

Local-regional recurrences: this will be assessed at one month after completion of radiotherapy then every three months for three years, then every six months for three years, then yearly thereafter.

Completion date

30/04/2010

Eligibility**Key inclusion criteria**

1. Informed consent
2. Women
3. Age 18 years or older
4. Histologically proven invasive breast carcinoma, stage I or II (T1-3N0 or T1-2N1M0, TNM 6th edition)
5. Surgery with clear margins
6. Pre-operative medical imaging (at least Computed Tomography [CT], Magnetic Resonance Imaging [MRI], and/or Positron Emission Tomography [PET]-scan)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Patients who do not match inclusion criteria
2. Prior breast or thoracic radiotherapy
3. Pregnancy or lactation
4. Fertile patients without effective contraception
5. Psychiatric or addictive disorders

Date of first enrolment

01/05/2007

Date of final enrolment

30/04/2010

Locations

Countries of recruitment

Belgium

Study participating centre

Oncologisch Centrum

Brussels

Belgium

1090

Sponsor information

Organisation

University Hospital Brussels (Universitair Ziekenhuis Brussel [UZ Brussel]) (Belgium)

ROR

<https://ror.org/038f7y939>

Funder(s)

Funder type

Charity

Funder Name

Foundation Against Cancer (Stichting tegen Kanker) (Belgium)

Results and Publications

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?
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[Results article](#)

results

16/05/2012

Yes

No