ISRCTN21164902 https://doi.org/10.1186/ISRCTN21164902

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	[X] Prospectively registered [_] Protocol
Registration date 13/04/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] 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

Contact name
Dr Vincent Vinh-Hung

Contact details
Oncologisch Centrum
UZ Brussel
Laarbeeklaan 101
Brussels
Belgium
1090
+32 (0)2 477 6041
conrvhgv@uzbrussel.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/05/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
118

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)

Sponsor details
c/o Dr Vincent Vinh-Hung
Radiotherapy-Oncology Department
Laarbeeklaan 101
Brussels
Belgium
1090
+32 (0)2 477 6041
conrvhgv@uzbrussel.be

Sponsor type
Hospital/treatment centre

Website
http://www.uzbrussel.be

ROR
https://ror.org/038f7y939

Funder(s)

Funder type
Charity

Funder Name
Foundation Against Cancer (Stichting tegen Kanker) (Belgium)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	16/05/2012		Yes	No