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Radiation dose intensity study in breast cancer in young women: a randomised phase III trial of additional dose to the tumour bed

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 14/02/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.trialsonline.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00212121

Secondary identifying numbers
1

Study information

Scientific Title
Radiation dose intensity study in breast cancer in young women: a randomised phase III trial of additional dose to the tumour bed

Acronym
Young Boost Trial

Study objectives
10 Gy additional boost to the tumour bed will yield an increase in local control at 10 years from 88% to 93%, with still acceptable cosmesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised active-controlled phase III 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
All patients will be treated with breast conserving therapy, followed by 50 Gy to the whole breast. Patients will be randomised to receive a boost dose of 16 Gy or 26 Gy to the tumour bed.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Local control at 10 years.

Secondary outcome measures
1. Cosmetic outcome
2. Additional objective is to test the genotypic and phenotypic profiles of breast tumours in young patients with invasive breast cancer, and its relation to:
2.1. Local recurrence after Breast Conserving Therapy (BCT)
2.2. Lymph node metastases
2.3. Distant metastases and survival
2.4. Radio sensitivity
2.5. Age
3. To determine whether improved genotypic and phenotypic profiles can be determined related to the endpoints mentioned in A

Overall study start date
01/07/2004

Completion date
01/07/2009

Eligibility

Key inclusion criteria
1. Age 50 years or younger
2. Histological diagnosis of invasive mammary cancer including all subtypes of invasive adenocarcinoma
3. Tumour location and extension imaged prior to surgery using at least mammography and ultrasound
4. Unicentric tumours and multifocal tumours removed using a wide local excision; microscopic radical resection (focally involved margins allowed, defined as: any Ductal Carcinoma In Situ [DCIS] or invasive carcinoma in three or fewer low-power fields (using a x 4 objective and a x 10 ocular lens, which has a diameter of 5 mm per low-power microscopic fields)
5. Sentinel lymph node biopsy and/or axillary lymph node dissection has been performed
6. Breast cancer stage: pT1-2pN0-2a M0
7. No treatment is allowed prior to surgery (no neoadjuvant chemotherapy, no neoadjuvant hormonal therapy, no pre-operative radiotherapy)
8. In cases where no adjuvant chemotherapy is given, wide local excision has been performed less than 10 weeks before the start of radiotherapy
9. In cases where adjuvant chemotherapy is given immediately after surgery, wide local excision has been performed less than 6 months before the start of radiotherapy, and chemotherapy should be completed less than 6 weeks before the start of radiotherapy
10. In cases where hormonal treatment is planned, this is given after completion of the radiotherapy
11. No previous history or synchronous malignant tumour in the other breast, previous history of malignant disease, except adequately treated carcinoma in situ of the cervix or basal cell carcinoma of the skin
12. Eastern Cooperative Oncology Group (ECOG) performance scale 2 or less

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
1160

Key exclusion criteria
1. Residual microcalcifications on mammogram
2. All histological types of malignancies other than invasive adenocarcinoma
3. In situ carcinoma of the breast, without invasive tumour
4. Concurrent pregnancy
5. Multicentric tumours, and multifocal tumours excised using multiple excisions
6. Invasive breast cancer in both breasts

Date of first enrolment
01/07/2004

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Nederlands Kanker Instituut/ Antoni van Leeuwenhoek Ziekenhuis, Plesmanlaan 121
Amsterdam
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1166 CX

Sponsor information

Organisation
Commission for Clinical Applied Research (Commissie voor Klinisch Toegepast Onderzoek [CKTO]) (The Netherlands)

Sponsor details

Sophialaan 8
Amsterdam
Netherlands
1075 BR

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Commission for Clinical Applied Research (Commissie voor Klinisch Toegepast Onderzoek - CKTO) (The Netherlands)

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?
Abstract results	results presented at 3rd ESTRO Forum :	01/04/2015	14/02/2019	No	No
Abstract results	results presented at Clinical Science Symposium:	01/04/2018	14/02/2019	No	No