A randomised Phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast

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To improve the outcome of women with non-low risk DCIS treated with breast conserving therapy. To individualise treatment selection for women with DCIS to achieve long term disease control with minimal toxicity

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON38251

Source
ToetsingOnline

Brief title
BOOG 2009-03/BIG 3-07/TROG 07.01/DCIS

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Ductal Carcinoma in Situ

Research involving
Human

Sponsors and support

Primary sponsor: European Organisation for Research in Treatment of Cancer (EORTC)

Source(s) of monetary or material Support: KWF kankerbestrijding;European Organisation Of Research and Treatment of Cancer (EORTC);Trans Tasman Radiaton Oncology Group (TROG)

Intervention

Keyword: BOOG 2009-03, boost, DCIS, radiotherapy

Outcome measures

Primary outcome

Time to local recurrence

Secondary outcome

Overall survival

Time to disease recurrence

Cosmetic outcome

Toxicity

Quality of life

Study description

Background summary

Since the introduction of mammographic screening for breast cancer, there has been a significant increase in the diagnosis of ductal carcinoma in situ (DCIS). The clinical approach to DCIS is predicated by experience with invasive breast cancer. This prospective randomised trial addresses an urgent clinical need to provide information for an evidence-based practice in the individualised management of women with DCIS. This will not only inform a consistent policy in the use of radiotherapy (RT) for DCIS but also have the potential to streamline the use of RT services. In addition, the psychological impact and quality of life consequences of the diagnosis and treatment of women with DCIS are poorly understood. The study will provide high quality research that is vital to the provision of appropriate psychosocial support for these women. The study will also form the basis for investigation of the essential biological nature of DCIS and identification of predictive biomarkers of treatment failure or toxicity that may provide useful clinical indicators in

the future.

Study objective

To improve the outcome of women with non-low risk DCIS treated with breast conserving therapy.
To individualise treatment selection for women with DCIS to achieve long term disease control with minimal toxicity

Study design

A multi-centre, non-blinded, phase III randomised trial.

Intervention

Randomisation B:
Arm 1: Whole breast RT alone: standard WB fractionation; 50 Gy/25 fractions/35 days
Arm 3: Whole breast RT standard WB fractionation plus tumour bed boost; 50 Gy/25 fractions/35 days
Boost 16 Gy/8 fractions/10 days

Randomisation C:
Arm 2: Whole breast RT alone shorter WB fractionation; 42.5 Gy/16 fractions/22 days
Arm 4: Whole breast RT, shorter WB fractionation plus tumour bed boost; 42.5 Gy/16 fractions/22 days
Boost 16 Gy/8 fractions/10 days

Study burden and risks

Quality of Life and cosmetic evaluation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Women with completely excised non-low risk DCIS of the breast treated by breast conserving surgery may be admitted to the study. Clinicians may enter patients onto the study, guided by individual equipoise, within the eligibility requirements of the study. ;- Women aged >=18 years ;- Histologically proven DCIS of the breast without an invasive component. ;- Bilateral mammograms performed within 6 months prior to randomisation. ;- Clinically node-negative. ;- Treated by breast conserving surgery (primary excision or re-excision) with complete microscopic excision and clear radial margins of 1 mm*.
*Patients with superficial or deep resection margin of < 1 mm are eligible if surgery has removed all of the intervening breast tissue from the subcutaneous tissue to the pectoralis fascia.;- Women who are at high risk of local recurrence due to: ;- Age < 50 years; OR
- Age 50 years plus at least one of the following:
Symptomatic presentation
Palpable tumour
Multifocal disease
Microscopic tumour size >= 1.5 cm in maximum dimension
Intermediate or high nuclear grade
Central necrosis
Comedo histology
Radial* surgical resection margin < 10 mm
*Patients with superficial or deep resection margin of < 10 mm are eligible if surgery has not removed all of the intervening breast tissue from the subcutaneous tissue to the pectoralis fascia. ;- Assessed by surgeon and radiation oncologist to be suitable for breast conserving therapy including whole breast RT. ;- Ability to tolerate protocol treatment. ;- Protocol RT should preferably commence within 8 weeks but must commence no later than 12 weeks

from the last surgical procedure. ;- ECOG performance status 0, 1 or 2. ;- Patient*s life expectancy > 5 years. ;- Availability for long-term follow-up. ;- Written informed consent.

Exclusion criteria

- Multicentric disease or extensive microcalcifications that could not be completely excised by breast conserving surgery with radial margins of 1 mm*.
*Patients with superficial and/or deep margin of < 1 mm are eligible if surgery has removed all of the intervening breast tissue from the subcutaneous tissue to the pectoralis fascia.

- Presence of tumour cells in lymph nodes detected using H & E or immunohistochemical examination (if lymph node biopsy or dissection has been performed). ;- Locally recurrent breast cancer. ;- Previous DCIS or invasive cancer of the contralateral breast. ;- Other concurrent or previous malignancies except: Non-melanomatous skin cancer; Carcinoma in situ of the cervix or endometrium; and Invasive carcinoma of the cervix, endometrium, colon, thyroid and melanoma treated at least five years prior to study admission without disease recurrence. ;- Serious non-malignant disease that precludes definitive surgical or radiation treatment (e.g. scleroderma, systemic lupus erythematosus, cardiovascular/pulmonary/renal disease). ;- ECOG performance status >=3. ;- Women who are pregnant or lactating.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-02-2010
Enrollment:	300

Type:	Actual

Ethics review

Approved WMO Date:	30-09-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-06-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00470236
CCMO	NL28754.091.09