Breast conserving surgery using Accelerated Partial Breast Irradiation in Elderly Patients with breast cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26007

Source
NTR

Brief title
elderly APBI

Health condition

Early stage breast cancer in elderly female patients.
age >=60 year
T1/2 N0 M0
Oudere vrouwen met borstkanker in een vroeg stadium
leeftijd >= 60 jaar

Sponsors and support

Primary sponsor: Radiotherapiecentrum West
Source(s) of monetary or material Support: Radiotherapiecentrum West / Partial funding through 'zorgvernieuwing' / MCHaaglanden

Intervention

Outcome measures

Primary outcome

Loco regional tumor control at 5 years.

Secondary outcome

1. (Loco regional) tumor control;

2. Side effects;

3. (Inter current) death;

4. Geriatric condition (questionnaires);

5. Co-morbidity and usage of medication.

Study description

Background summary

The treatment policy for elderly patients with early stage breast cancer is largely intuitive and is just partly based on evidence as these patients are often not included in phase II/III studies. As a consequence a relative large proportion is treated by breast ablation and sentinel node biopsy. Accelerated partial breast irradiation (APBI) either by intra-operative or external beam radiotherapy might be a good alternative for elderly patients offering less treatment burden in a shortened treatment time and a limited chance of recurrence. International studies using APBI claim equivalent tumor control and cosmetic results compared to conventional fractionated radiotherapy.

The elderly patient is a complex patient due to the age, the (geriatric) condition with frequent co-morbidity and usage of multiple medications. The collection of information of these (geriatric) conditions in Dutch radiotherapy centers will give us a solid base to construct algorithms to predict patient outcome (tumor related, morbidity and intercurrent disease).

Study objective

Local control and toxicity in breast conserving therapy using APBI is not inferior to classical 50 Gy irradiation.

Study design

1. Before surgery;

2. 3, 6 and 12 months after surgery;

3. Yearly until death.

Intervention

Depending on the facilities of the centre either:

1. Intra-operative radiotherapy at lumpectomy (21 Gy 90% isodose, “ELIOT procedure”);

2. Postoperative external beam radiotherapy (3DCRT or IMRT, 10x3,4 Gy ICRU, 10 fractions in 2 weeks).

Contacts

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Eligibility criteria

Inclusion criteria

1. Histological confirmed breast cancer (DCIS and invasive) subtypes;

2. T1 as determined by ultrasound;

3. T2 smaller than 30 mm as determined by ultrasound, ER/PR + Herneu --, + or ++;

3. N0 on palpation / ultrasound examination; pN1mi, pN1a (by axill.lymphnode dissection)

Unicentric, Unifocal disease (radiological), multifocal when limited within 2 cm;

4. Age 60 or older;

5. Any hormonal receptor status, hormonal therapy allowed cf Dutch treatment guidelines;

6. Technically eligible for lumpectomy or radiotherapy;

7. No contra indications for lumpectomy and sentinel node procedure;

8. Written informed consent;

9. Willing to fill out the QOL, geriatric Q and comorbidity questionnaires.

Exclusion criteria

1. Patients not eligible / fit for lumpectomy and sentinel node procedure;

2. T2 smaller than 30 mm and triple negative or Her2neu +++;

3. pT2(>30 mm), pT3 and pT4;

4. Positive surgical margins;

5. Multi centricity; multifocal (> 2cm from the index lesion);

6. Extensive intraductal carcinoma; lympho-vascular invasion;

7. Previous treatment of ipsilateral breast tumor (DCIS or invasive);

8. Paget disease of the nipple;

9. Distant metastases; > pN2a (4 or more positive axillary lymphnodes);

10. Previous radiotherapy on the thoracic region;

11. (Neo adjuvant) chemotherapy or other Cytotoxic medication;

12. Collagen diseases (systemic erythematosus lupus, scleroderma, dermatomyositis);

13. Psychiatric diseases or other that prevents signing of informed consent;

14. Other neoplasm’s in the last 5 year with exception of skin tumors (excl melanoma) and intraepithelial lesions of the cervix uteri.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-01-2011
Enrollment:	710
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-06-2011
Application type:	First submission

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
NTR-new	NL2791
NTR-old	NTR2931
Other	METC ZuidwestHolland : 10-042
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Intraoperative radiotherapy during breast conserving surgery; a study on 1822 cases treated with electrons. Veronesi et al, B4reast Cancer Res Treat. 2010 Nov;124(1):141-51. Epub 2010 Aug 15. PMID: 20711810