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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26007

Bron
NTR

Verkorte titel
elderly APBI

Aandoening

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

Ondersteuning

Primaire sponsor: Radiotherapiecentrum West
Overige ondersteuning: Radiotherapiecentrum West / Partial funding through 'zorgvernieuwing' / MCHaaglanden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Loco regional tumor control at 5 years.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

1. Before surgery;

2. 3, 6 and 12 months after surgery;

3. Yearly until death.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-01-2011
Aantal proefpersonen:	710
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2791

Register	ID
NTR-old	NTR2931
Ander register	METC ZuidwestHolland : 10-042
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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