A study on the use of a subcutaneous injection to reduce skin side effects of breast brachytherapy with palladium seeds.

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

Samenvatting

ID

NL-OMON23164

Bron
Nationaal Trial Register

Verkorte titel
PBSI trial

Aandoening

breast cancer, brachytherapy, skin toxicity, spacer

mammacarcinoom, brachytherapie, huidtoxiciteit, spacer

Ondersteuning

Primaire sponsor: Franciscus Gasthuis en Vlietland
Erasmus MC- Kanker Instituut
Overige ondersteuning: investigator initiated
funding by Stichting Theia, Stichting Coolsingel and Franciscus Vriendenfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Occurrence of teleangiectasia, following Bentzen's four point scale (LENTSOMA), after 2 years.

Toelichting onderzoek

Achtergrond van het onderzoek

1 out of 8 women develop breast cancer. Breast conserving therapy has been shown to be as effective as ablative therapy in the treatment of a selected group of early stage breast cancer patients. Postoperative irradiation of the breast is part of the breast conserving therapy. Along with the fact that local recurrences usually occur close to the primary tumor, this stimulated worldwide research on various forms of partial breast irradiation and cosmesis and quality of life.With Permanent Breast Seed Implant (PBSI), a form of brachytherapy, radioactive seeds are implanted percutaneously into the surgical cavity. Palladium103 seeds, with a halflife of 16.8 days, and a therapeutic dosage after 84 days, appear to be the most appropriate for this purpose. 5year results of several multicentre trials on Permanent Breast Seed Implant (PBSI) were reported in 2015. In total, 134 patients with early stage invasive breast cancer were treated with a permanent breast seed implant as the sole adjuvant radiation treatment after breast conserving surgery. The trials accrued patients based on the guideline for accelerated partial breast irradiation (APBI) of the American Society for Radiation Oncology (ASTRO). The outcomes included overall and diseasefree survival and local recurrence at 5 years. The true local recurrence rate was compared using 2tailed paired t tests for control estimates calculated using the Tufts University ipsilateral breast tumor recurrence and Memorial Sloan Kettering ductal carcinoma in situ nomograms. The observed local recurrence rate at a median followup period of 63 months was 1.2%, similar to the estimate for whole breast irradiation (1.4% p=0.23), The 5year overall survival rate was 97.4% SD ± 1.9%, and the disease free survival rate was 96.4% SD ± 2.1%.

The most common side effects of PBSI are skinrelated. Acute skin toxicity comprises a moist desquamation in 16% with PBSI, which is lower than with WBI. Late skin toxicity leads to fibrosis and induration or telangiectasia. The latter occurs in 25% of the patients after PBSI, slightly more than after WBI5. Telangiectasia corresponds to the dilation of an abnormal neovasculature in the skin following the destruction of normal capillaries by the radiation treatment. Due to their prominent appearance, telangiectasia have a negative effect on cosmesis, the patient’s body image and quality of life. Therefore, interventions to reduce the clinical appearance of telangiectasia may impact a patient’s overall wellbeing or quality of life. The use of a subcutaneously injected spacer, to increase the distance between the

radiation sources and the skin, could reduce skin toxicity after PBSI. Studies in patients with prostate cancer who underwent brachytherapy, show that the use of a hyaluronic acid spacer reduced rectal dose. This spacer is reabsorbed in 6 to 12 months and is not associated with an increased risk of infection. Hyaluronic Acid is widely used as a dermal filler in cosmetic industry. The use of a spacer in breast cancer patients has never been done before. In this study the effect of a hyaluronic acid spacer on skin toxicity after PBSI will be investigated in a randomized controlled trial. All patients in the study will receive PBSI as sole adjuvant radiation therapy with or without spacer injection, depending on their treatment allocation. The primary outcome measure is the occurrence of telangiectasia at two years. In addition, the effect of PBSI on cosmesis, quality of life (both patientreported), wound infection, local recurrence and (disease free) survival and cost effectiveness will be assessed and compared to a comparable group of patients getting standard radiation treatment. This will be the first study on PBSI in Europe. If the results of this study are favourable, PBSI can be a very patientfriendly and costeffective alternative for external whole breast irradiation in breast conserving therapy.

Doel van het onderzoek

We hypothesize that injecting an inert/biodegradable spacer between the dermis and the most superficial layer of the planned target volume (PTV) could remove the skin from the high dose volume, and this would result in a significant reduction of telangiectasia at 2 years.

Onderzoeksopzet

primary outcome: 1 and 2 years

secondary outcomes:

local recurrence, disease free and overall survival (1,2,3,4,5,10y)

induration (Baseline, 2months, 1y, 2y)

wound infection (3m)

cosmetic results and health related quality of life (BL, 6M, 1-5y)

costeffectiveness (1y)

Validation of a Dutch translation of the BCTOS questionnaire

Onderzoeksproduct en/of interventie

subcutaneous injection of 5-10ml hyaluronic acid (Barrigel of Restylane SubQ) as a spacer during PBSI

Intervention group receives PBSI treatment with spacer injection, control group receives PBSI

without spacer injection.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Female

• Age 50 years or above

• A confirmed histological diagnosis of invasive ductal carcinoma (IDC) or DCIS

• Treated by breast conserving surgery with axillary node dissection (with a minimum of 6 nodes sampled) or sentinel lymph node biopsy

• A maximum tumor size of 3 cm

• Clear surgical margins at ink for IDC and ≥ 2 mm for DCIS or re-excision negative

• PBSI technically feasible

• Node negative (axillary lymph node dissection or sentinel node biopsy)

• Informed consent signed

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Lymphovascular invasion

• Known allergy for hyaluronic acid

• Neo-adjuvant chemotherapy

• Active auto immune disorder with severe vasculitis component

• Uncontrolled and complicated diabetes insulin-dependent

• Pregnancy

• Cosmetic breast implants

• Psychiatric or addictive disorder that would preclude attending follow-up

• Post-operative wound infection or abscess following CDC criteria

• Lobular features on histology (pure or mixed) or sarcoma histology

• Extensive in situ carcinoma

• Multicentric disease (in more than one quadrant or separated by 2 cm or more)

• Paget’s disease of the nipple

• Metastases or active other cancer

• Patients presenting with a post-surgical fluid cavity ≥ 2.5 cm in diameter in the direction of implanted needled as determined on the planning US, resistant to 4 weeks of hot compresses application

• Clear delineation of the target volume on CT is not possible (WBR recommended)

• Having a volume to be implanted over 150cc

• Having a target volume too close to skin such that the 90% isodose overlaps the skin surface

• Inability to read Dutch

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2017
Aantal proefpersonen:	231
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-06-2017
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	NL6365
NTR-old	NTR6549
Ander register	ABR: NL56210.078.16 : MEC-2016-400 METC Erasmus MC

Resultaten