Partial Breast Radiotherapy in Low-risk Breast cancer group using a MR-guided adaptive approach; a phase II study

Gepubliceerd: 04-02-2020 Laatst bijgewerkt: 18-08-2022

This novel MRgRT approach of PBI-delivery with daily plan adaptation for breast cancer limits radiation doses to surrounding normal organs and thereby potentially reduce radiation-induced toxicity.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26191

Bron
Nationaal Trial Register

Verkorte titel
PARLOB

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VUmc
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Early and early-delayed toxicity (CTCAE v. 4.0)

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of this study is to investigate the early and early-delayed toxicity in patients treated with partial breast irradation (PBI) after local excision for low risk breast cancer. PBI is given to the tumorbed plus margin as five treatments over a 2 weeks period using MR-guided radiotherapy (MRgRT)

Doel van het onderzoek

This novel MRgRT approach of PBI-delivery with daily plan adaptation for breast cancer limits radiation doses to surrounding normal organs and thereby potentially reduce radiation-induced toxicity.

Onderzoeksopzet

Follow-up of 1.5year after breast conserving surgery, according to national guidelines for radiation oncology

Onderzoeksproduct en/of interventie

Patients will be treated using MRgRT in a course of 5 fractions of 6 Gy or 6.5 Gy, depending on tumor characteristics, per fraction in two weeks overall treatment time. The MRIdian treatment delivery system (ViewRay, USA), which will be used for this study, allows for imaging with superior soft-tissue contrast for localizing the surgical cavity and surrounding normal organs, such as heart, lung and glandular breast tissue prior to delivering each fraction. This allows for adaptive planning, which is optimized for the size and location of the target volume relative to normal organs for each fraction. In addition, while continuously imaging, the MRIdian delivery platform allows for ‘markerless’ gating, i.e. radiation beam-on only when the target is in the predetermined position. All these aspects allow for the use of small uncertainty margins, thereby potentially decreasing treatment-related toxicity.

Contactpersonen

Publiek

Amsterdam UMC, location VUmc

Shyama Tetar

+31 (0)20 4440413

Wetenschappelijk

Amsterdam UMC, location VUmc
Shyama Tetar

+31 (0)20 4440413

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Good candidates for partial breast irradiation according to the GEC-ESTRO recommendations are patients selected in the low-risk group. In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age > 50 years
- WHO performance score 0-2
- Pathology proven breast cancer with following histology: invasive ductal carcinoma, mucinous, tubular, medullary, colloid cc, and associated LCIS
- Any histologic grade
- Any hormonal receptor status
- T-stage: Tumor size ≤ 3cm (pT1-2)
- N-stage: No positive lymph nodes examined by sentinel lymph node biopsy or axillary lymph node dissection (at least 6 nodes pathologically examined)
- Radical resection of tumor with ≥ 2mm surgical margin free of tumour
- All patients should be able to undergo MRI scans
- Ability to provide written informed consent.
- Ability to perform breath-hold for at least 17 seconds

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

According to the GEC-ESTRO recommendations, subject who meets any of the following criteria will be excluded from participation in this study:
- Breast cancer histology of invasive lobular carcinoma, ductal carcinoma in situ sec
- Breast cancer with a multicentric or multifocality character
- An extensive intraductal component in pathology examination
- Lympho-vascular invasion in the pathology examination

- Treatment with neoadjuvant chemotherapy before lumpectomy
- Breast conserving surgery with an oncoplastic breast surgery technique
- Re-excision of tumour in ipsilateral breast
- Open surgical wound or wound infection
- Previous irradiation in the ipsilateral breast
- Contra-indications for MRI

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-10-2017
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-02-2020
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	NL8351
Ander register	METc VUmc : METc 2016.463, Toetsingonline NL58704.029.16

Resultaten