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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26191

Source
Nationaal Trial Register

Brief title
PARLOB

Health condition

Breast cancer

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Cosmetic outcome (panel scoring, BCCT.core software and patient self-evaluation) and quality of life (EORTC-QoL C30 & Breast Cancer module QLQ BR23)

Study description

Background summary

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)

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
Amsterdam UMC, location VUmc
Shyama Tetar

+31 (0)20 4440413
Scientific
Amsterdam UMC, location VUmc
Shyama Tetar

+31 (0)20 4440413

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2017
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-02-2020
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	NL8351
Other	METc VUmc : METc 2016.463, Toetsingonline NL58704.029.16

Study results