Pilot study: the use of PET-MRI in work-up of breast cancer patients.

Published: 12-11-2014
Last updated: 21-04-2024

The primary objective of this study is to evaluate the ability of PET-MRI (PET, DWI and DCE-MRI) to detect and locally stage breast cancer in patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON41083

Source
ToetsingOnline

Brief title
Pilot study: the use of PET-MRI in work-up of breast cancer patients.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breastcancer

Research involving
Human

Sponsors and support

Primary sponsor: Radiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breastcancer, MRI, PET-MRI

Outcome measures

Primary outcome

The primary goal is technical and clinical feasibility; to assess feasibility of PET-MRI in breast cancer patients with regards to patient comfort in relation to a prolonged prone position, evaluation of robustness of image quality.

Patient satisfaction concerning the PET-MRI will be examined with a questionnaire (appendix 1).

The image quality will be assessed by 2 Nuclear Medicine physicus and radiologists.

Secondary outcome

nvt

Study description

Background summary

Neoadjuvant chemotherapy (NAC) is one of the standard therapies for locally advanced breast cancer. Several randomized controlled trials have shown that NAC is as effective as adjuvant chemotherapy and that patients subjected to NAC are more likely to undergo breast-conserving surgery, without compromising oncologic outcomes. Moreover, the use of NAC permits the in-vivo monitoring of the tumor response and identification of patients in which further treatment may be necessary.
Clinically, it has been established that only complete pathological remission after NAC has adequate clinically relevant prognostic power. The challenge for imaging will be to identify non-responding patients much earlier during treatment and to characterize the nature of this resistance. There is ample evidence to suggest that MRI (DWI, DCE) and PET (18F-FDG) predict pathological response NAC. However, current results of either technique when performed in isolation are far from perfect.
There is a clinical need to understand whether and how information from these techniques might improve overall prediction, and to investigate the mechanisms

of resistance. This requires image guided biopsies of PET and MRI signals obtained in a comprehensive manner to allow for a thorough analysis of signal heterogeneity. PET-MRI is the only hybrid technique for such research. For PET, our initial focus will be put on 18F-FDG, but other tracers that assist in phenotyping the disease (FES, FDHT, 89Zr-trastuzumab) are also available, to be implemented beyond technical feasibility phases.

Study objective

The primary objective of this study is to evaluate the ability of PET-MRI (PET, DWI and DCE-MRI) to detect and locally stage breast cancer in patients.

Study design

Feasibility pilot study:
All these patients will routinely (as standard of care) undergo a PET- CT after the diagnosis of breast cancer and a MRI of the breast. Instead of the routine MRI a combined PET-MRI will be made within 90 minutes after the PET-CT.
The extra burden is the prolonged scantime in prone position during the PET-MRI compared to the breast MRI of 10-20minutes.
There is no additional exposure to radiation and the patients only need a single dose of FDG for both PET-CT and PET-MRI.

Study burden and risks

All participating patients will receive routine follow-up imaging of the NAC according to normal standards in the VU University Medical Center (breast MRI before, sometimes after 3 cycles of NAC and pre-surgery). The extra burden is the prolonged scantime in prone position during the PET-MRI compared to the breast MRI.
There is no additional exposure to radiation and the patients only need a single dose of FDG for both PET-CT and PET-MRI.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

breastcancer

Exclusion criteria

claustrophobia

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	12-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL49709.029.14